DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 864, 868, 870, 872, 876, 880, 882, 884, 888, and 890

[Docket No. 95N–0084]

RIN 0910–AA31

Medical Devices; Effective Date of Requirement for Premarket Approval for Class III Preamendments Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for 43 class III medical devices. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA is announcing the opportunity for interested persons to request the agency to change the classification of any of the devices based on new information.

DATES: Written comments by January 5, 1996; request for a change in classification by September 22, 1995. FDA intends that, if a final rule based on this proposed rule is issued, PMA's will be required to be submitted within 90 days of the effective date of the final rule.

ADDRESSES: Submit written comments or requests for a change in classification to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4765.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. For the sake of convenience, this preamble refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as ''preamendments devices.''

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the act is not required to have an approved investigational device exemption (IDE) (21 CFR part 812) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

Section 515(b)(2)(A) of the act provides that a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The proposed rule; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed rule and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change of classification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, section 515(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, issue a final rule to require premarket approval, or publish a notice terminating the proceeding. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is made final, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or a notice of completion of a PDP for any such device be filed within 90 days of the date of promulgation of the final rule or 30 months after final classification of the device under section 513 of the act, whichever is later. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of the device in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the class III devices that are the subjects of this regulation.

The act does not permit an extension of the 90-day period after promulgation of a final rule within which an application or a notice is required to be filed. The House Report on the amendments states that ''the thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket

approval.'' (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976).)

The Safe Medical Devices Act of 1990 (Pub. L. 101–629) (SMDA) added new section 515(i) to the act (21 U.S.C. 360e(i)). This section requires FDA to review the classification of preamendments class III devices for which no final rule has been issued requiring the submission of PMA's and to determine whether each device should be reclassified into class I or class II or remain in class III. For devices remaining in class III, SMDA directed FDA to develop a schedule for issuing regulations to require premarket approval. However, the SMDA does not prevent FDA from proceeding immediately to rulemaking under section 515(b) of the act on specific devices, in the interest of public health, independent of the procedures in section 515(i). Indeed, proceeding directly to rulemaking under section 515(b) of the act is consistent with Congress' objective in enacting section 515(i) i.e., that preamendments class III devices for which PMA's have not been required either be reclassified to class I or class II or be subject to the requirements of premarket approval. Moreover, in this proposal, interested persons are being offered the opportunity to request reclassification of any of the devices.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA issued a notice of availability of a preamendments class III devices strategy document. The strategy document set forth FDA's plans for implementing the provisions of section 515(i) of the act for preamendments class III devices for which FDA had not yet required premarket approval. FDA divided this universe of devices into three groups:

1. Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness but are no longer used or are very limited in use. FDA's strategy is to call for PMA's for all Group 1 devices in an omnibus 515(b) rulemaking action. This proposed rule implements that strategy and covers all Group 1 devices referenced by the May 6, 1994, **Federal Register** notice.

2. Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. For these devices, FDA has issued an order under section 515(i) of the act requiring manufacturers to submit safety and effectiveness information so that FDA can make a determination as to whether the devices should be reclassified.

3. Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA intends to issue proposed rules to require the submission of PMA's for the 15 highest priority devices in this group in accordance with the schedule set forth in the strategy document. FDA has also issued an order under section 515(i) of the act for the remaining 27 Group 3 devices requiring the submission of safety and effectiveness information so that FDA can make a determination as to whether the devices should be reclassified or retained in class III.

A. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for class III devices within 90 days after promulgation of any final rule based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing such class III devices during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days of the date of filing. FDA cautions that, under section 515(d)(1)(B)(i) of the act, the agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the agency finds that ''* * * the continued availability of the device is necessary for the public health.''

FDA intends that, under § 812.2(d) (21 CFR 812.2(d)), the preamble to any final rule based on this proposal will state that, as of the date on which a PMA or a notice of completion of a PDP is required to be filed, the exemptions in § 812.2(c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any device that is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA or notice of completion of PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or a notice of completion of a PDP for a class III device is not filed with FDA within 90 days after the date of promulgation of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations regarding significant risk devices are met. The requirements for significant risk devices include submitting an IDE application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period after the final rule to avoid interrupting investigations.

B. Proposed Finding With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP; and (2) the benefits to the public from the use of the device.

These findings are based on the reports and recommendations of the advisory committees (panels) for the classification of these devices along with any additional information that FDA discovers. Additional information can be found in the proposed and final rules classifying these devices as listed below:

Devices	Proposed rule	Final rule
Hematology/ Pathology (21 CFR part 864).	September 11, 1979 (44 FR 52950).	September 12, 1980 (45 FR 60576
Anesthesi- ology 1982 (21 CFR part 868).	November 2, 1979 (44 FR 63292).	July 16, (47 FR 31130)
Cardio- vascular (21 CFR part 870).	March 9, 1979 (44 FR 13284).	February 5, 1980 (45 FR 7904)
Dental (21 CFR part 872).	December 30, 198 (45 FR 85962).	August 12, 1987 (52 FR 30082)
Gastro- enterology- Urology (21 CFR part 876).	January 23, 1981 (46 FR 7562).	November 23, 1983 (48 FR 53012)
General Hos- pital and Personal Use (21 CFR part 880).	August 24, 1979 (44 FR 49844).	October 21, 1980 (45 FR 69678)
Neurological (21 CFR part 882).	November 28, 1978 (43 FR 55640).	September 4, 1979 (44 FR 51726)
Obstetrical and Gyne- cological.	April 3, 1979(44 FR 19894).	February 26, 1980 (45 FR 12682)

Devices	Proposed rule	Final rule
Orthopedic (21 CFR part 888).	July 2, 1982 (47 FR 29052).	September 4, 1987 (52 FR 33686)
Physical Medicine (21 CFR part 890).	August 28, 1979 (44 FR 50458).	November 23, 1983 (48 FR 53032)

C. Devices Subject to This Proposal

1. Hematology and Pathology Devices

Automated Differential Cell Counter (§ 864.5220)

(1) *Identification*. An automated differential cell counter is a device used to identify and classify one or more of the formed elements of the blood. The device is in class III when intended for uses other than to flag or identify specimens containing abnormal blood cells. Otherwise, the device is in class II.

(2) *Summary of data*. The members of the Hematology and Pathology Devices Classification Panel based their recommendation upon the Panel members' clinical experience with automated differential cell counters and on information presented at a symposium entitled ''Differential Counters in Hematology'' held at the Panel meeting. Among the speakers at the symposium was Dr. Robert Miller of the Johns Hopkins University Medical Center. Dr. Miller discussed difficulties concerning data interpretation, precision and accuracy, correlation to reference methods and error in terms of coincidence, nonreproducible results, nonlinearity, and specific interferences.

FDA has reviewed medical literature concerning automated differential cell counters (Refs. 1 through 5). The medical literature reports two basic methodologies for automated differential cell counting: Pattern recognition and flow-through techniques. Pattern recognition systems microscopically scan a fixed, stained blood film. Flow-through systems count and identify cells suspended in a liquid medium.

Pattern recognition systems are handicapped by their lack of accuracy (Ref. 1). In one study, 68.8 percent of the abnormal cells that the system examined were classified as normal (Ref. 2). An error of this sort could result in the failure to detect a pathological blood sample (Ref. 1). Several studies (Refs. 3 through 5) show a discrepancy between pattern recognition counts and manual counts of monocytes (mononuclear leukocytes). It is suggested that the criteria for identifying monocytes need to be better defined (Ref. 4). There also have been reports of discrepancies between pattern recognition counts and manual counts of plasma cells and atypical lymphocytes (Ref. 4). The tendency of pattern recognition systems to underestimate the number of atypical lymphocytes is ascribed to flaws in the recognition criteria. Pattern recognition systems also cause difficulty in blood film preparation. Overlapping cells must be avoided, and a uniform distribution of cell types must be achieved (Ref. 1).

Flow-through systems allow a hundredfold increase in the rate at which cells are counted. There is imperfect correlation between the classification logic systems of the flow-through machines and morphological features of the blood cell classes as defined by fixed, Romanowsky-stained preparations (Ref. 1). Therefore, these machines will fail to classify up to 10 percent of normal cells.

The device was the subject of a reclassification petition and was partially reclassified into class II for the uses listed above. The proposed rule for reclassification was published in the **Federal Register** of April 5, 1989 (54 FR 13698) and the final rule was published in the **Federal Register** of June 8, 1990 (55 FR 23510).

(3) *Risks to health*.

• Hepatitis infection—Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection. HIV was unknown in 1979 when the device was classified and is also an important risk.

• Misdiagnosis and inappropriate therapy—Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a blood cell disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

2. Anesthesiology Devices

Electroanesthesia Apparatus (§ 868.5400)

(1) *Identification*. An electroanesthesia apparatus is a device used for the induction and maintenance of anesthesia during surgical procedures by means of an alternating or pulsed electric current that is passed through electrodes fixed to the patient's head.

(2) *Summary of data*. The Anesthesiology Devices Classification Panel and the Neurological Devices Classification Panel recommended that electroanesthesia apparatus be classified into class III (premarket approval) because the device presents a potential unreasonable risk of illness or injury to the patient. The Anesthesiology Devices Classification Panel based its recommendation on the insufficient number of domestic studies on human subjects. The Panel had not seen any medical data on which to judge the safety and effectiveness of the device, and believed that the technique of electroanesthesia is not considered a well-established or well-recognized clinical procedure. The Neurological Devices Classification Panel noted that many factors important to the clinical application of this technique have not been sufficiently defined. The Neurological Devices Classification Panel also based its recommendation on the Panel members' experience with the device, and their judgment and knowledge of the pertinent literature (Ref. 6). The National Research Council recommended that electroanesthesia should be considered as a potentially useful adjunct in the maintenance of anesthesia but that electroanesthesia should be limited to investigational use until its effects, advantages, and standardization can be adequately evaluated.

(3) *Risks to health*.

• Electrical shock—Improper electrical grounding may allow the patient or operator to receive an electrical shock.

• Damage to central nervous system—Excessively high electrical current or voltage could damage the central nervous system and cerebral tissues.

• Skin burns—If the electrodes are too small and yield a high current density, skin burns may result.

• Skin irritation—Electrode gels or pastes used to establish electrical contact between the electrode and the skin may cause skin irritation.

• Cardiac or pulmonary interference—The position of the electrode on the head may lead to electrical interference with cardiac or pulmonary functions in the patient.

3. Cardiovascular Devices

Catheter Balloon Repair Kit (§ 870.1350)

(1) *Identification*. A catheter balloon repair kit is a device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to effect the repair or replacement.

(2) *Summary of data*. The members of the Cardiovascular Devices Classification Panel based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. The Panel was not aware of any published literature on this device.

(3) *Risks to health.*

• Gas embolism—Balloon rupture caused by the repair material or a leak in the repair material can allow potentially debilitating or fatal gas emboli to escape into the bloodstream.

• Embolism—Pieces of the balloon that break or flake off may form potentially debilitating or fatal emboli.

• Thromboembolism—Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboemboli.

• Cardiac arrhythmias—Toxic substances released from the repair material (glue or other adhesive) can trigger cardiac arrhythmias (irregularities in heart rhythm).

Trace Microsphere (§ 870.1360)

(1) *Identification.* A trace microsphere is a radioactively tagged nonbiodegradable particle that is intended to be injected into an artery or vein and trapped in the capillary bed for the purpose of studying blood flood within or to an organ.

(2) *Summary of data.* The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

(3) *Risks to health.*

• Thromboembolism—Inadequate blood compatibility of the materials used in the device may lead to potentially debilitating or fatal thromboemboli.

• Embolism—If the microspheres are too large or tend to clump together, they can lodge in a blood vessel and block the flow of blood to an organ.

• Tissue damage—Tissue damage can result from excessive radioactivity of the particles.

Carotid Sinus Nerve Stimulator (§ 870.3850)

(1) *Identification.* A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.

(2) *Summary of data.* The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

(3) *Risks to health.*

• Tissue and blood damage—If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood and tissue may result.

• Inability to control blood pressure—Failure of the device to stimulate properly can prevent effective control of elevated blood pressure.

High-Energy DC-Defibrillator (Including Paddles) (§ 870.5300)

(1) *Identification.* A high-energy DC-defibrillator is a device that delivers into a 50-ohm test load an electrical shock of greater than 360 joules of energy used for defibrillating the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

(2) *Summary of data.* The Panel relied upon the potential hazards associated with the inherent properties of the device and on the Panel members' personal knowledge of, and experience with, the device. In addition, the Panel sought information from the medical and scientific community, industry, and medical literature (Refs. 20 through 25).

(3) *Risks to health.*

• Electrical shock to operator—Improper electrical design of the device can lead to a serious electrical shock to the operator.

• Inability to defibrillate or persistence of the arrhythmia—Inability to rhythmia may occur because of excessive energy, excessive current, insufficient energy, insufficient current, a difference between the indicated level of energy and the delivered into a 50-ohm load, or excessive leakage current.

• Inability to defibrillate—Inability to defibrillate may occur when certain drugs that can raise the defibrillation threshold are used.

• Inability to defibrillate due to paddle design—Inability to defibrillate may result from inappropriate paddle size or inappropriate paddle location on the subject.

4. Dental Devices

Karaya and Sodium Borate With or Without Acacia Denture Adhesive (§ 872.3400)

(1) *Identification.* A karaya with sodium borate with or without acacia denture adhesive is a device composed of karaya and sodium borate with or without acacia intended to be applied to the base of a denture before the denture is inserted into the patient's mouth. The device is used to improve denture retention and comfort. If it contains 12 percent or more by weight of sodium borate, it is in class III; otherwise it is in class I.

(2) *Summary of data.* The members of the Dental Devices Classification Panel relied upon their personal knowledge of, and clinical experience with, the device in the practice of dentistry and on a report from the then-Bureau of Drugs' OTC Panel on Dentifrices and Dental Care Agents (Ref. 26). This report states that there is a lack of information concerning the safety of adhesives containing sodium borate and a lack of information concerning the effectiveness of acacia in denture adhesives. The report states that the sodium borate concentration of 12 to 20 percent of the adhesive's total weight is equivalent to 2.6 to 5.3 percent boron. Because at least a portion of a denture adhesive is ingested, this amount of boron could cause chronic toxicity in denture wearers (Ref. 27). The Panel agrees that there is a lack of data concerning the safety and effectiveness of acacia and karaya with sodium borate.

(3) *Risks to health.*

• Chronic toxicity—The boron in this device may cause chronic toxicity to users.

• Adverse tissue reaction—If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Carboxymethylcellulose Sodium and Cationic Polyacrylamide Polymer Denture Adhesive (§ 872.3420)

(1) *Identification.* A carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive is a device composed of carboxymethylcellulose sodium and cationic polyacrylamide polymer intended to be applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(2) *Summary of data.* The Panel based its recommendation on the lack of information available to demonstrate the effectiveness of carboxymethylcellulose sodium and cationic polyacrylamide in dental adhesives and on a report of the then-Bureau of Drugs' OTC Panel on Dentifrices and Dental Care Agents. According to the report, the belief that carboxymethylcellulose sodium is safe is based, in part, on its widespread use in food products such as milk and ice cream (Ref. 28). Tests of cationic polyacrylamide for acute oral toxicity, eye irritation, and dermal and inhalation toxicity in subacute and chronic feeding experiments in animals have been negative (Ref. 26). Human patch tests also have been negative (Ref. 28). However, no data were submitted to the Panel to demonstrate, and the literature did not establish, the effectiveness of carboxymethylcellulose

sodium cationic polyacrylamide polymer as a denture adhesive.

(3) *Risks to health.*

• Bone loss from lack of effectiveness—If the adhesive fails to anchor the denture in its proper position, a change in the distance between the upper and lower jaws may occur that may lead to gum irritation and bone loss due to alteration of biting forces.

• Adverse tissue reaction—if the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Polyacrylamide Polymer (Modified Cationic Denture Adhesive (§ 872.3480)

(1) *Identification.* A polyacrylamide polymer (modified cationic) denture adhesive is a device composed of polyacrylamide polymer (modified cationic) intended to be applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(2) *Summary of data.* The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device, and on a report of the then-Bureau of Drugs' OTC Panel on Dentifrices and Dental Care Agents. Tests of polyacrylamide polymer (modified cationic) for acute oral toxicity, eye irritation, and dermal and inhalation toxicity in subacute and chronic feeding experiments in animals have been negative (Ref. 26). Human patch tests also have been negative (Ref. 28). However, no data were submitted to the Panel to demonstrate, and the literature did not establish, the effectiveness of polyacrylamide polymer as the sole ingredient of a denture adhesive.

(3) *Risks to health.*

• Bone loss—If the adhesive fails to anchor the denture in its proper position, and the distance between the upper and lower jaw is changed, then bone loss and gum irritation may occur.

• Adverse tissue reaction—If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Polyvinylmethylether Maleic Anhydride (PVM–MA), Acid Copolymer, and Carboxymethylcellulose Sodium (NACMC) Denture Adhesive (§ 872.3500)

(1) *Identification.* Polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive is a device composed of polyvinylmethylether maleic anhydride, acid copolymer, and carboxymethylcellulose sodium intended to be applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(2) *Summary of data.* The Panel based it recommendation on the Panel members' personal knowledge of, and clinical experience with the device and on a report of the then-Bureau of Drugs' OTC Panel on Dentifrices and Dental Care Agents. The report states that sufficient data are not available to demonstrate the safety and effectiveness of a combination of PVM—MA and NACMC used as a denture adhesive (Ref. 26). The Panel also based its recommendation on a publication by Blacow (Ref. 27), which states that the pH and stability of the anhydride and diacid forms may be hazardous due to the possible presence of an acid pH of 2 to 3, which can burn the tissues in the mouth.

(3) *Risks to health.*

• Toxicity—Ingestion of the materials in this device may cause chronic toxicity to users.

• Adverse tissue reaction—If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction. Acidity of the adhesive may burn tissues in the mouth.

Over-the-Counter (OTC) Denture Reliner (§ 872.3560)

(1) *Identification.* An OTC denture reliner is a device consisting of a material such as plastic resin that is intended to be applied as a permanent coating or lining on the base or tissue-contacting surface of a denture. The device is intended to replace a worn denture lining and may be available for purchase over the counter.

(2) *Summary of data.* The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The Panel also based its recommendation on statements that further studies are necessary to determine the safety and effectiveness of this device (Ref. 26).

(3) *Risks to health.*

• Bone degeneration—Use of the device may cause alteration in the vertical dimension of a denture and result in bone degeneration in the upper and lower jaw.

• Carcinomas—Long-term irritation or oral tissues caused by incorrect vertical dimension may cause formation of carcinomas.

Root Canal Filling Resin (§ 872.3820)

(1) *Identification.* A root canal filling resin is a device composed of material, such as methylmethacrylate, intended for use during endodontic therapy to fill the root canal of a tooth. If chloroform is used as an ingredient in the device, the device is in class III. Otherwise, it is in class I.

(2) *Summary of data.* The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, root canal filling resins in the practice of dentistry.

(3) *Risks to health.* FDA believes that root canal fillings containing chloroform present a risk of carcinogenicity.

5. Gastroenterology-Urology Devices

Colonic Irrigation System (§ 876.5220)

(1) *Identification.* A colonic irrigation system is a device intended to instill water into the colon through a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon. The system is designed to allow evacuation of the contents of the colon during the administration of the colonic irrigation. The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled. The device may include a console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes. The device may use electrical power to heat the water. This device does not include the enema kit (§ 876.5210). When the device is intended for colon cleansing when medically indicated, such as before radiologic or endoscopic examinations, it is in class II. When the device is intended for other uses, including colon cleansing routinely for general well being, it is in class III.

(2) *Summary of data.* The members of the Gastroenterology-Urology Devices Classification Panel based their recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

(3) *Risks to health.*

• Tissue burns—The temperature-regulating mechanism for the water heater used in this device may allow overheating of the water which is delivered to the patient's colon, resulting in tissue burns.

• Perforation of the colon—Excessive water pressure delivered by this device could result in perforation of the wall of the colon.

• Colon irritation—Excessive or inappropriate use of this device may result in irritation of the colon.

• Electrical injury—Improper design, construction, or a malfunction of the device could result in electrical injury to the patient or operator.

Implanted Electrical Urinary Continence Device (§ 876.5270)

(1) *Identification*. An implanted electrical urinary continence device is a device intended for treatment of urinary incontinence that consists of a receiver implanted in the abdomen with electrodes for pulsed-stimulation that are implanted either in the bladder wall or in the pelvic floor, and a battery-powered transmitter outside the body.

(2) *Summary of data*. The Panel based its recommendation on a review of the historical data concerning implanted electrical urinary continence devices. Halverstadt and Parry (Ref. 29) discussed several unsolved problems inherent in the electrical stimulation of the bladder. These problems include breakage of lead wires, the cumbersome nature of the electrodes, risk of preformation by wires of the bladder cavity, difficulty of obtaining uniform contraction of the detrusor muscle, and the spread of the stimulus to neighboring tissues producing abdominal pain. The Panel also based its recommendation on the experimental nature of these devices and on the lack of adequate medical literature and experience supporting their safety and effectiveness.

(3) *Risks to health*.

• Adverse tissue reaction and erosion—Defects in the design or the construction of the device, or lack of biocompatibility of the materials used in the device, may cause an adverse tissue reaction and tissue erosion adjacent to the device.

• Infection—Defects in the design or construction of the device preventing adequate cleaning or sterilization, or defects in packaging or processing of a device sold as sterile, may allow pathogenic organisms to be introduced and cause an infection in the patient.

• Tissue damage—Defects in the electrode wires may lead to their breakage and consequent tissue damage.

• Abdominal and leg pain—The amount of stimulation by the electrodes necessary to obtain adequate bladder stimulation may lead to abdominal and leg pain.

• Electrical injury—Improper design, construction, or malfunction of the device could result in electrical injury to the patient or the operator.

6. General Hospital and Personal Use Devices

Chemical Cold Pack Snakebite Kit (§ 880.5760)

(1) *Identification*. A chemical cold pack snakebite kit is a device consisting of a chemical cold pack and tourniquet used for first-aid treatment of snakebites.

(2) *Summary of data*. The members of the General Hospital and Personal Use Devices Classification Panel based their recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on several articles in the literature that evaluate different types of treatment for snakebites (Refs. 30, 31, and 32). Most of the literature showed that cryotherapy (the use of cold therapy for the treatment of snakebites) is inappropriate. Clement and Pietrusko found high rates of amputation, local tissue destruction, and prolonged disability in patients treated by this method (Ref. 30). A National Academy of Sciences report stated that doubts about the safety and effectiveness of short-term cold therapy for treatment of snakebites have not been resolved (Ref. 31). The report also stated that the use of cold therapy for a long period of time appears to be dangerous. Watt reported that, among children who had to have amputations because of snakebites, 75 percent had received cryotherapy for the snakebites (Ref. 32).

(3) *Risks to health*.

• Local tissue damage—Exposure of tissue to cold temperatures for long periods of time can freeze the tissue and cause local tissue damage, sometimes necessitating limb amputations.

7. Neurological Devices

Rheoencephalograph (§ 882.1825)

(1) *Identification*. A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area.

(2) *Summary of data*. The members of the Neurological Devices Classification Panel referenced the literature on this device (Refs. 43 through 46). Some of the panel members witnessed its clinical application. Dr. William Jarzembski, one of the Panel members, provided some detailed information concerning his research on this device.

(3) *Risks to health*.

• Erroneous clinical conclusions—The device may indicate that cerebral circulation is normal, when in fact it may be very abnormal.

• Electrical shock—Excessive current could cause injury, and malfunction of the device could result in an electrical shock.

• Skin reaction—The electrode materials and conductive media may irritate the skin.

Intravascular Occluding Catheter (§ 882.5150)

(1) *Identification*. An intravascular occluding catheter is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels) of intracranial blood vessels.

(2) *Summary of data*. The Panel members based their recommendation on the lack of data available on this device. Although the Panel members were aware of the use of this device in investigational programs, they believed that there is not enough information or data to demonstrate that its safety and effectiveness can be adequately controlled by means other than premarket approval.

(3) *Risks to health*.

• Infarction of nervous tissue—If the catheter is not controllable or if the balloon or tip should fail or unexpectedly come loose from the catheter, use of the device may cause infarction of nervous tissue (death of nervous tissue due to stoppage of circulation) and other serious injury to the brain and other nervous tissue.

• Hemorrhage—The catheter or improper balloon inflation may injure a blood vessel and result in bleeding.

• Thrombogenesis—Blood coagulation and clotting may result if the material of which the catheter is constructed is not compatible with blood.

Implanted Spinal Cord Stimulator for Bladder Evacuation (§ 882.5850)

(1) *Identification*. An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(2) *Summary of data*. The Panel members based their recommendation on information supplied by Dr. Blaine Nashold, one of the Panel members, who had been one of the primary individuals engaged in the development of the device (Ref. 37). Dr. Nashold reported that he had implanted the device in a small group of paraplegic patients. Six of the 12 patients had been successfully emptying their bladders by this method for 5 years (Ref. 37).

(3) *Risks to health*.

• Injury to neural tissue—Tissue fibrosis may develop around the electrode on the spinal cord and cause a diminished response to the electrical stimulus.

• Tissue toxicity—The implanted stimulator, lead wires, or electrodes may contain material that is not biocompatible.

• Cerebrospinal fluid leakage—The fluid that surrounds the spinal cord might leak out around the receiver wires.

8. Obstetrical and Gynecological Devices

Obstetric Data Analyzer (§ 884.2050)

(1) *Identification*. An obstetric data analyzer is a device designed to interpret fetal status during labor and to warn of possible fetal distress by analyzing electronic signal data obtained from fetal or maternal electronic or other monitors. This generic type of device includes signal analysis and display equipment, electronic interfaces for other equipment, and power supplies and component parts.

(2) *Summary of data*. FDA reviewed the Obstetrical and Gynecological Devices Classification Panel's recommendation and obtained additional information and data describing the application of automatic analysis techniques to the determination of possible fetal distress. The technique was new in 1978, and very little definitive information was available. It was reasonable to expect that as algorithms were developed and tested, confidence in automatic analysis would increase (Ref. 38).

(3) *Risks to health*.

• Electrical shock—Malfunction of the device could result in electrical shock to the patient.

• Misdiagnosis—Inadequate design or calibration of the device could lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data is used in managing the patient, the physician may prescribe a course of treatment which places the fetus and patient at risk unnecessarily.

Fetal Electroencephalographic Monitor (§ 884.2620)

(1) *Identification*. A fetal electroencephalographic monitor is a device used to detect, measure, and record in graphic form (by means of one or more electrodes placed transcervically on the fetal scalp during labor) the rhythmically varying electrical skin potentials produced by the fetal brain.

(2) *Summary of data*. The Panel based its recommendation on the fact that fetal electroencephalographic monitoring was a relatively new method of brain function evaluation during birth. Its sensitivity and applicability in the field of the fetal brain research remained to be established because clinical experience was too limited to ascertain its safe and effective use. Rosen and Peltzman, who were performing the major research on this device, were continuing with further controlled studies (Refs. 39 and 40).

(3) *Risks to health*.

• Electrical shock—Malfunction of the device could result in electrical shock to the patient.

• Misdiagnosis—Inadequate design of the device can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the fetus and patient at risk unnecessarily.

• Adverse tissue reaction—Material in the device could result in a systemic or local tissue reaction when the device comes in contact with the patient.

• Infection—If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Fetal Scalp Clip Electrode and Applicator (§ 884.2685)

(1) *Identification*. A fetal scalp clip electrode and applicator is a device designed to establish electrical contact between fetal skin and an external monitoring device by means of pinching skin tissue with a nonreusable clip. This device is used to obtain a fetal electrocardiogram. This generic type of device may include a clip electrode applicator.

(2) *Summary of data*. The Panel based its recommendation on personal knowledge of, and experience with, the device. Information presented to the Panel indicated a 1 to 2 percent infection rate for newborns on whom fetal scalp clip electrodes were used (Ref. 41). The Panel noted that this device is in limited use in the United States because the circular (spiral) electrode, preferred because it is easier to apply and remove, is available.

(3) *Risks to health*.

• Adverse tissue reaction—Material in the device could cause a local tissue or systemic reaction when the device comes in contact with the fetus.

• Infection—If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

• Tissue damage—Poor design or incorrect application could result in scalp injury when the device pinches the fetal scalp.

Expandable Cervical Dilator (§ 884.4250)

(1) *Identification*. An expandable cervical dilator is an instrument with two handles and two opposing blades used manually to dilate (stretch open) the cervix.

(2) *Summary of data*. The Panel based its recommendation on personal knowledge of, and experience with, the device. The Panel members' experience with the expandable cervical dilator had been that its leverage is very difficult to control in such a way that the cervix is dilated evenly.

(3) *Risks to health*.

• Laceration of the cervix—Appropriate design and materials are necessary to prevent trauma to the cervix and possible subsequent infertility.

• Adverse tissue reaction—Material in the device could cause a local tissue or systematic reaction when the device comes in contact with the patient.

• Infection—If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Vibratory Cervical Dilator (§ 884.4270)

(1) *Identification*. A vibratory cervical dilator is a device designed to dilate the cervical os by stretching it with a power-driven vibrating probe head. The device is used to gain access to the uterus or to induce abortion, but is not to be used during labor when a viable fetus is desired or anticipated.

(2) *Summary of data*. The Panel based its recommendation on experience with, and personal knowledge of, the device. The Panel reviewed the literature on the device and in a typical study of 50 patients, there were 3 failures to dilate and 3 patients with cervical tears (Ref. 42). The Panel believed that more data concerning these types of dilators were necessary before standards could be written.

(3) *Risks to health*.

• Laceration of the cervix—Appropriate design and material are necessary to prevent trauma to the cervix and possible subsequent infertility.

• Electrical shock—Malfunction of the device could result in electrical shock to the patient.

• Adverse tissue reaction—Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient.

• Infection—If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

Metreurynter-Balloon Abortion System (§ 884.5050)

(1) *Identification*. A metreurynter-balloon abortion system is a device used to induce abortion. The device is inserted into the uterine cavity, inflated, and slowly extracted. The extraction of the balloon from the uterus causes dilation of the cervical os. This generic type of device may include pressure sources and pressure controls.

(2) *Summary of data*. The Panel based its recommendation on the Panel members' familiarity with the device and a review of the literature on this device. Although journal articles discussing the use of this device in Japan indicate that it may be safe and effective (Refs. 43 and 44), the Panel believed that these data were inconclusive and that more studies needed to be performed to establish the performance characteristics of the device. A standard textbook mentioned that the device is rarely used because of potential trauma or infection, unpredictability, and the risk of a live-born fetus (Ref. 45).

(3) *Risks to health*.

• Infection—If the device is not properly sterilized, it may introduce microorganisms that could cause infection.

• Trauma, laceration, hemorrhage, and perforation—Poor design of the device could cause uneven dilation of the cervix causing injury to the patient.

• Adverse tissue reaction—Material or substances in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient's cervix.

• Unnecessary medical procedures—Loss of the device could result in an otherwise unnecessary medical procedure to recover the device from the uterus.

Abdominal Decompression Chamber (§ 884.5225)

(1) *Identification*. An abdominal decompression chamber is a hoodlike device used to reduce pressure on the pregnant patient's abdomen for the relief of abdominal pain during pregnancy or labor.

(2) *Summary of data*. The Panel based its recommendation on personal knowledge of, and experience with, this device. The Panel considered this device to be ineffective. Additionally, the Panel found no literature available to supply adequate clinical data supporting any claim of effectiveness. The consensus of the Panel was that any data that might be developed would support an action to ban the device because its risks outweigh its benefits.

(3) *Risks to health*.

• Difficult patient management—The device is cumbersome and covers the abdominal area of the patient, thus blocking the physician from examining the patient.

• Supine hypotension—Because the patient is required to lie on her back, the possibility of induced low blood pressure and consequent complications exists.

9. Orthopedic Devices

Ankle Joint Metal/Polymer Non-Constrained Cemented Prosthesis (§ 888.3120)

(1) *Identification*. An ankle joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a tibial component made of alloys, such as cobalt-chromium-molybdenum, and a talar component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(2) *Summary of data*. The members of the Orthopedic Devices Classification Panel based their recommendation on the Panel members' personal knowledge of the device and on the available medical literature. According to Freeman (Ref. 47), ''It is still too early to say whether this operation (total ankle joint replacement) offers any advantages over arthrodesis * * *. It would appear a comfortable mobile ankle can be produced but how reliably this can be done and how long the results will last is impossible to say.'' The only available clinical study on the device at the time of the Panel meeting had been done by Newton (Ref. 48). From 1973 to 1978, 50 patients had this prosthesis implanted. There have been 20 (40 percent) reported failures. FDA believed these data are insufficient to establish the safety and effectiveness of ankle joint metal/polymer non-constrained prostheses.

(3) *Risks to health*.

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Elbow Joint Humeral (Hemi-Elbow) Metallic Uncemented Prosthesis (§ 888.3180)

(1) *Identification*. An elbow joint humeral (hemi-elbow) metallic uncemented prosthesis is a device intended to be implanted, made of alloys such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri. The generic type of device is limited to prostheses intended for use without bone cement (§ 888.3027).

(2) *Summary of data*. The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The only available clinical data at the time of the Panel meeting were the results of 2 surgeons who had implanted 18 devices over a 10-year period (Ref. 49). An earlier publication (Ref. 50) discussed the clinical results in what appeared to be the first 10 of these 18 implantations. The devices had been implanted in nine patients (one patient had prostheses implanted bilaterally). These patients were evaluated 1 to 7 years later and only four patients (44 percent) had stable, pain-free elbows with a functional range of motion. New bone growth restricted or totally blocked elbow joint motion in three patients. The device was removed in two other patients; because of joint pain and swelling in one; and because the device had dislocated and was eroding through the skin in the other.

(3) *Risks to health*.

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in the loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and release of materials from the device to the

surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Finger Joint Metal/Metal Constrained Uncemented Prosthesis (§ 888.3200)

(1) *Identification.* A finger joint metal/metal constrained uncemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal (MCP) or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device includes prostheses made of alloys, such as cobalt-chromium-molybdenum, or protheses made from alloys and ultra-high molecular weight polyethylene. This generic type of device is limited to prostheses intended for use without bone cement (§ 888.3027).

(2) *Summary of data.* The only finger joint metal/metal constrained uncemented prosthesis discussed in the literature at the time of the Panel meeting was a two-pronged stainless steel hinged prostheses that was developed by Flatt for use in the MCP and the proximal interphalangeal (PIP) joints of the fingers.

Flatt presented clinical results with the Flatt finger prosthesis in a series of publications over a 12-year period (Refs. 51 through 56). Thirty-one prostheses had been implanted for 6 months or more (6 months to 34 months); 23 in the PIP joint and 8 in the MCP joint. In the earliest of these reports, Flatt noted that despite early encouraging clinical results, the long-term outlook for the device did not look favorable. In particular, Flatt noted that the bone absorption that occurs around the neck of the prosthesis may possibly lead to obstruction of flexion. Flatt also noted that possible complications from use of the device might be: (a) Bone erosion in patients in whom the intramedullary prongs have been forced together in the medullary canal, and (b) metal fatigue and fracture of the intramedullary prongs.

Subsequent publications by Flatt (Refs. 55 and 56) showed that the predicted complications did, in fact, occur. Flatt and Ellison (Ref. 55) reported on the implantation of 242 prostheses (167 in the MCP joint and 75 in the PIP joint) with an average followup of 6.2 years (range 1 to 12 years). Twenty-six (10.7 percent) of the prostheses (15 MCP and 11 PIP) had to be removed for the following reasons: Periarticular fibrosis (bone resorption) and settling, 14; failure (i.e., fracture) of both intramedullary prongs, 2; failure of the screw holding the hinge together, 2; breakdown of the skin over the prosthesis, 5; and infection, 3. The authors reported that of the prostheses that required removal, more than half were removed because of settling within the recipient bones. Bone absorption around the intramedullary prongs, scarring, or heterotrophic bone formation around the hinge caused sufficient mechanical difficulties to necessitate removal of the prosthesis. Flatt and Ellison noted that the gradually progressing periarticular fibrosis (bone resorption) resulted in a decreased range of joint motion and was related to very active use of the hand.

Girzados and Clayton (Ref. 57) reported on the implantation of 23 Flatt finger prostheses in 11 patients with an average followup of 44 months (range 24 to 73 months). Of the 23 prostheses implanted, 11 were in the MCP joints of the fingers, 8 were in the PIP joints of the thumb. Bone absorption around the neck and stems of the prosthesis occurred in 16 of the 23 (69 percent) joints. Six prostheses (26 percent) were rated as poor results: Three had no motion postoperatively; one was grossly unstable; and two were implanted in a patient with active rheumatoid disease who, over a period of 64 months, had intermittent swelling and pain over the joints that had been replaced with the prostheses. The authors reported that ''good'' or ''fair'' results were obtained in 13 (56 percent) of the joints. However, the number of patients having pain-free stable joints with a useful range of motion (defined as ''good'') as opposed to those with limited motion, minimal pain, and instability (defined as ''fair'') could not be determined.

Problems associated with the Flatt finger prosthesis have been recognized by many authors (Refs. 58 through 63). Several authors (Refs. 58 and 59) reported that these prostheses have not been generally accepted because of the accompanying bone resorption. McFarland (Ref. 60) reported that the Flatt prosthesis had been only moderately successful, that complications were frequent and included bone overgrowth with loss of motion, migration of the prosthesis due to bone erosion, and metal failures (i.e., device fractures). Goldner and Urbaniak (Ref. 62) and Smith and Broudy (Ref. 63) noted that the bone resorption and subsequent migration of the devices was caused by the use of a rigid material in osteoporotic bone. Smith and Broudy (Ref. 63) also noted that the intramedullary prongs frequently migrate through the cortex and occasionally the hinge would break or the overlying skin would ulcerate, causing tendon rupture and infection.

(3) *Risks to health.*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Finger Joint Metal/Metal Constrained Cemented Prosthesis (§ 888.3210)

(1) *Identification.* A finger joint metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a MCP (finger) joint. This device prevents dislocation in more than one anatomic plane and has components which are linked together. This generic type of device include prosthesis that are made of alloys, such as cobalt-chromium-molybdenum, and is limited to those prosthesis intended for use with bone cement (§ 888.3027).

(2) *Summary of data.* Two types of these prostheses were discussed in the literature: (a) The Link prostheses, a metallic hinge intended to replace the MCP joint of a finger or thumb; and (b) the Biomedical Laboratories of the University of Cincinnati (BLUC) prostheses, a hinged metallic prostheses intended to replace the MCP joint of the thumb.

Devas and Shah (Refs. 64 and 65) reported on the implementation of 51 Link prostheses in 25 patients with an average postoperative followup of 4 years (range 2 to 6 years). In 15 (30 percent) of these implantations, the patient had persistent pain in the joint and what was described as a useless finger. The authors believed that the proportion of patients with pain was far too large to make the treatment method freely available. They noted that the main cause of failure was due to loosening of the prostheses with disruption (erosion) of the bone. They also noted that in most of the joints with good and fair results the prosthesis had become loose but that the patients were free from symptoms at the time of

evaluation. The authors believed that prosthesis loosening may have been caused by fixation of the components by injecting the cement into the metacarpal and phalangeal bone shafts, and it was noted that a modified prosthesis with a different technique of insertion was being considered (Ref. 65). Two papers (Refs. 66 and 67) described the design and testing of the BLUC thumb prostheses. Clinical results, however, were not presented. FDA believed that the data available on the devices, the clinical results of the use of the devices in 25 patients with a reported failure rate of 30 percent, and the recommendation by the authors that the procedure not be made freely available, did not establish the long-term safety and effectiveness of finger joint metal/metal constrained prostheses.

(3) *Risks to health*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Finger Joint Metal/Polymer Constrained Cemented Prosthesis (§ 888.3220)

(1) *Identification.* A finger joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace a MCP or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane, and consists of two components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(2) *Summary of data.* Clinical results on three designs of finger joint polymer constrained prostheses were presented in the literature: The Calnan-Nicolle prosthesis, intended for use in the MCP and PIP joints for the fingers; the Niebauer prosthesis also intended for use in the MCP and PIP joints of the fingers; and the Swanson prosthesis intended for use in the MCP and PIP joints of the fingers and for the MCP joint of the thumb.

a. *Calnan-Nicolle prosthesis.* This device has two components: An across-the-joint component having intramedullary stems and a flexible hinge made of polypropylene, and a silicone rubber sleeve which encapsulates the flexible hinge portion of the device (Ref. 72). Griffiths and Nicolle (Ref. 73) reported on the clinical results 8 to 37 months (average of 20 months) after implantation of the Calnan-Nicolle device in 112 MCP joints in 31 patients. Complete relief from pain was obtained in four (13 percent) patients. There was much improvement over preoperative pain status in 13 (42 percent), moderate pain relief in 10 (32 percent), and little pain relief in 4 (13 percent) patients. These authors reported that a deterioration in the performance of the prosthesis occurred in up to half of the patients between 1 and 2 years after insertion of the prosthesis; and that part of the deterioration in function was due directly to mechanical failure of the prosthesis. The range of joint motion had deteriorated over time in 33 of the 40 (82.5 percent) hands on which surgery was performed. Joint deformity was ''corrected and held'' in 10 to 31 hands (32 percent), was corrected initially but recurred in 14 of 31 (45 percent) hands, and worsened in 7 of 31 (23 percent) hands. The silicone capsule (sleeve) had fractured in 31 of the 112 prostheses (28 percent). The polypropylene stems had fractured in five joints (5 percent). Nicolle (Ref. 71) noted that time and experience had shown that the polypropylene hinge of the Calnan-Nicolle prosthesis does not appear to be strong enough to withstand fully the compression and torsional stresses that may occur in the use of the hand.

b. *Niebauer prosthesis.* This device consists of a single, flexible, across-the-joint component. The intramedullary stems and the flexible hinge portion of the device are made of silicone to allow tissue penetration and fixation of the stems. Beckenbaugh et al. (Ref. 75) reported on the clinical results 12 to 65 months (average 32 months) after implantation in the MCP joints of 68 Niebauer prostheses and found a fracture rate of the device of 38.2 percent (26 devices), recurrence of clinical deformity in 44.1 percent (30 devices) and recurrence of pain in 2 percent. Goldner et al. (Ref. 76) reported a fracture rate of 29.7 percent in 37 prostheses implanted for 6.5 years and 17.5 percent fracture rate in 143 prostheses implanted 4 to 6 years. These authors believe that the silicone-polyester material used in the device may absorb lipids and become brittle, and that eventual fracture of the prosthesis is a possibility, but that fracture does not preclude a good functional result. Goldner and Urbaniak (Ref. 77) evaluated 103 patients over a 4-year period. Pain was relieved or greatly diminished postoperatively in all but 8 of the 103 patients. The average active range of motion in these patients was 51 degrees. The range of motion was noted to increase up to about 1 year postoperatively; and then thought to decrease slightly, possibly due to enlarged bony outgrowths from the surface of the bone and impingement of peripheral bone on the hinge of the device. In two (2 percent) of patients, the device had fractured, which was accompanied by deformity and a moderate amount of pain.

Hagert (Ref. 78) conducted X-ray examinations on 41 joints with Niebauer implants. This author reported that of the 41 prostheses studied, 26 (63.4 percent) were found to be damaged (i.e., cracked within the implant midsection, fragmented at the midsection, or fractured at the hinge), 1 to 36 months postoperatively. This author believed that the Niebauer implant might be too weak to withstand forces in the MCP joints, and that a possible contributing factor was the use of materials (polyester fiber and silicone rubber) with differing elasticity. This author noted that the Niebauer implant was reported to have withstood 100 million flexions during mechanical tests bending it around a fixed axis, but not exposing it simultaneously to shearing type forces which are present in the MCP joint. These shearing forces were reportedly most probably responsible for the deformation of the implant and the subsequent damage observed. Niebauer and Landry (Ref. 79) reported that destruction of the bone around the hinge of the device had occurred in a few cases and that this atrophy may be the result of pressure from the prosthesis. In an evaluation by X-ray of the 41 Niebauer prostheses, Hagert (Ref. 78) observed bone resorption in 23 of the 41 joints (56 percent). The cortex of the bone was penetrated in 13 (32 percent) of these joints. It was reported that the observed erosion of the bone is most likely caused by motion of the intramedullary stems within the medullary cavity, and is exaggerated by the rough polyester surface of the device.

c. *Swanson prosthesis.* This device is made entirely of silicone rubber and is

designed to act as an internal mold, maintaining joint alignment, becoming encapsulated and stabilized by fibrous tissue, and gliding or moving within the medullary cavity rather than being fixed to the bone (Ref. 80). A number of reports (Refs. 75 and 80 through 86) were found describing the use of the Swanson prostheses in the MCP joints of the fingers, but few reports (Refs. 87 through 90) were available describing the use of this device in the MCP joint of the thumb, or the PIP joints of the fingers. In 1976, it was reported that a new ''high performance'' silicone elastomer material had been developed for use in the Swanson prosthesis. With the exception of one report (Ref. 90), the available clinical data were obtained using prostheses made from the ''conventional'' silicone elastomer. Fracture of implants made of the ''conventional'' silicone elastomer appears to be the most frequently reported failure. Beckenbaugh et al. (Ref. 75) reported that of 186 Swanson prostheses implanted in the MCP joint for an average of 32 months (range 12 months to 65 months), 26.3 percent (49) had fractured. Hagert et al. (Ref. 82) reported that of 104 Swanson implants evaluated, 25 percent (26) had failed, either by cracking or fragmenting and fracturing within the followup period of 1.5 to 5 years. Mannerfelt and Anderson (Ref. 83) reported a fracture rate of 2.8 percent in 144 joints evaluated 1.5 to 3.5 years (average 2.5 years) after implantation. Ferlic et al. (Ref. 84) reported a fracture rate of 9 months (average 2.3 years) after implantation. Swanson (Ref. 80) reported the lowest rate of fracture, 0.88 percent, in a field clinic series involving over 3,000 implants with a followup of from 6 to 30 months.

The effects of fracture of the device on the clinical results were evaluated by several authors. Aptekar et al. (Ref. 85) described the occurrence of detritic synovitis (inflammation of the synovial tissue) due to shards of silicone rubber found in relation to a broken prosthesis. Beckenbaugh et al. (Ref. 75) noted that recurrence of deformity was associated with implant fracture, i.e., ulnar drift, in 14 percent; weakness or instability in 21 percent; hyperextension in 11 percent; and some clinical deformities in 43 percent; but that while the recurrence of deformity implied that soft tissue balance was not present after the implant fractured, it was not clear whether the imbalance caused the fracture or developed because of it.

Hagert (Ref. 86) believed that the increased displacement, i.e., ulnar deviation, noted in some joints with fractured implants, may indicate insufficiency of the fibrous capsule surrounding the implant to restrain the forces occurring at the MCP joint. This pressure, combined with movement of the implant within the medullary canal was reportedly found to cause a moderately progressive bone resorption throughout the followup period in all of the 36 joints examined. Resorption was observed around the midsection of the prosthesis where the implant was in close contact with bone and around the intramedullary stems of the device. Erosion of bone around the midsection of the device led to various degrees of migration of the device in 28 out of 36 (78 percent) of the joints examined. The author found that decreased joint flexion was observed due either to the distal migration of the implant or a growing volar bony spur in 13 out of the 39 (33 percent) joints examined. He concluded that the design of the device may be insufficient to fully restrain the volarly and proximally directed forces in the MCP joint and the serious decrease of flexion. Hagert et al. (Ref. 82) reported that although it is generally accepted that silicone rubber absorbs lipids and other substances, the effects on material changes and degradation is not adequately known. Weightman et al. (Ref. 87) noted that lipid absorption could contribute to mechanical failure of the prostheses, as chemical deterioration is known to be a prime initiator of fatigue failures of polymers. Other clinical results have been reported in the literature (Refs. 80, 81, 87, and 89) on the use of this prosthesis in large numbers of patients. These results were very similar to those summarized previously.

(3) *Risks to health*.

- Loss or reduction of joint function—Improper design of inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.
- Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.
- Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Hip Joint Metal Constrained Cemented or Uncemented Prosthesis (§ 888.3300)

(1) *Identification*. A hip joint metal constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have components made of alloys, such as cobalt-chromium-molybdenum, and is intended for use with or without bone cement (§ 888.3027). This device is not intended for biological fixation.

(2) *Summary of data*. The agency has obtained data and information describing the use of hip joint metal constrained prostheses. Sivash (Ref. 91) reported on implantation in 164 patients; followup time was 1 to 9 years. Breakage of the prosthesis was reported in 13 (8 percent) of the patients. Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believed that use of the hip joint metal constrained prosthesis presents an unreasonable risk of illness or injury.

(3) *Risks to health*.

- Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device, or loosening of the device in the surgical cavity.
- Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to a dissolution or wearing away from the surfaces of the device and the release of material from the device to the surrounding tissues and systemic circulation.
- Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis (§ 888.3310)

(1) *Identification*. A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such

as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene. This generic type of device is intended for use with or without bone cement (§ 888.3027). This device is not intended for biological fixation.

(2) *Summary of data.* The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

(3) *Risks to health.*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Hip Joint (Hemi-Hip) Acetabular Metal Cemented Prosthesis (§ 888.3370)

(1) *Identification.* A hip joint (hemi-hip) acetabular metal cemented prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have an acetabular component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(2) *Summary of data.* The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

(3) *Risks to health.*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Hip Joint Femoral (Hemi-Hip) Trunnion-Bearing Metal/Polyacetal Cemented Prosthesis (§ 888.3380)

(1) *Identification.* A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis is a two-part device intended to be implanted to replace the head and neck of the femur. This generic type of device includes prostheses that consist of a metallic stem made of alloys, such as cobalt-chromium-molybdenum, with an integrated cylindrical trunnion bearing at the upper end of the stem that fits into a recess in the head of the device. The head of the device is made of polyacetal (polyoxymethylene) and it is covered by a metallic alloy, such as cobalt-chromium-molybdenum. The trunnion bearing allows the head of the device to rotate on its stem. The prosthesis is intended for use with bone cement (§ 888.3027).

(2) *Summary of data.* The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a presentation to the Panel. Dr. Ian Goldie (University of Goteborg) presented the results of several Norwegian studies with these prostheses. Dr. Goldie referred to Christiansen's series of 241 hips in which excellent results were obtained in 57 percent of the cases and good results in 33 percent. In this series, there were five infections, seven cases of loosening of the acetabular cup, two dislocations shortly after operation, two cases of femoral perforation, and three cases of heterotopic ossification. Dr. Goldie then presented the results of his own series of 61 patients. In the 19 patients with 2 years followup, and in the 28 patients with 6 months followup, there were no complications. However, in the remaining 14 patients with a followup of 1 year, there were the following complications: 2 dislocations between the head and the cup, 2 cases of heterotopic ossification, and 2 patients with inexplicable pain.

FDA sought additional data and information on the safety and effectiveness of these devices. A review of the medical literature revealed a disagreement regarding the resistance to wear of polyacetal materials. McKellop et al. (Ref. 92) reported that laboratory wear rates for polyacetal ranged from 70 percent lower than polyethylene to 540 percent higher. Dumbleton (Ref. 93) reported wear in the trunnion sleeve of the device and that polyacetal exhibits a low resistance to wear. Because of the potential problems involving its resistance to wear, the long-term effectiveness of this device is questionable. The initial investigator and his associates have been the primary users of this device. Long-term followup data are available only from the initial investigator. Clinical cases documenting effectiveness and safety of the device involve usage of less than 3 years.

(3) *Risks to health.*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction in joint function due to excessive wear, fracture, deformation of the device components, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of a prosthesis within the body may lead to an increased risk of infection.

Knee Joint Femorotibial Metallic Constrained Cemented Prosthesis (§ 888.3480)

(1) *Identification.* A knee joint femorotibial metallic constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. The only knee joint movement allowed by the device is in the sagittal plane. This generic type of device includes prostheses that have an intramedullary stem at both the proximal and distal locations. The upper and lower components may be joined either by a solid bolt or pin, an internally threaded bolt with locking screw, or a bolt retained by circlip. The components of the device are made of alloys, such as cobalt-chromium-molybdenum. The stems of the device may be perforated, but are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(2) *Summary of data.* The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device, and its

review of the medical literature. Results from using the device in more than 720 cases have been reported in the medical literature in the United States during the past 3 years (Refs. 94, 100, and 103). Reports in the medical literature exist that document use of the device in several thousand cases worldwide during the past 10 years. The Panel believed that this extensive clinical use has revealed the usual mechanical problems, implant loosening and settling. The Panel determined that the overall risks resulting from use of the prosthesis were no worse than the risks associated with major knee surgery without implantation of a prosthesis.

Of the 957 patients reviewed by the Panel who have had this prosthesis implanted and who were discussed in the worldwide medical literature (Refs. 94 through 105), 108 (11 percent) suffered implant failure, 233 (24 percent) of the cases had complications, and 104 (11 percent) had loosening of the prosthesis.

FDA sought additional data on the safety and effectiveness of this device. Kettelkamp (Ref. 105) reported that the failure rate for the device ranges from 5 percent to 24 percent for the hinged metal knee prosthesis, with a short followup time. Kettlekamp (Ref. 105) and Chand (Ref. 106) both believe that excessive forces may be applied to the intramedullary stem bone cement interface because the constrained prosthesis hinge prevents medial/lateral joint movement. Kettlekamp believes that if the stem loosens, the cement may rub away and destroy the surrounding bone, causing a larger cavity and making revision difficult or impossible.

Kettlekamp reviewed reports in the medical literature on use of 576 Walldius hinged knee prostheses. In one group of 144 implantations, complications occurred in 29 cases (13 percent). In the remaining 432 cases, 89 (20 percent) were classified as failures, 33 (7 percent) required reoperations, and 53 (12 percent) had loosening. Fractures occurred in 11 cases (2 percent) and deep infection was reported in 35 knees (8 percent). Kettlekamp reported that the incidence of complication increased with the length of reported followup. Brady and Garber (Ref. 103) reviewed results of implanting the Shiers design of this device in 288 knees. He reported poor results in 71 knees (24 percent), reoperation was required in 33 knees (11 percent), and loosening observed in 56 knees (19 percent). Brady stated that the major problems involved with use of these prosthesis are the absence of axial (medial) rotation, the necessary resection of large amounts of bone, and the creation of physiologic dead space.

Kettlekamp (Ref. 105) and Deburge et al. (Ref. 107) reported that the major problem with the Shiers design prosthesis is loosening. Deburge reported a loosening rate of 15 percent (22 patients) during a 5-year followup of the request of implanting the Guepar constrained knee prosthesis in 152 patients. However, less than half of these instances of device loosening were symptomatic (10 of 22 patients). Reoperations were performed on the 10 patients. Other authors (Ref. 100) believed that the rate of loosening of the prosthesis is higher, possibly around 80 percent, but that only a small percentage of those patients with device loosening are symptomatic.

Arden and Kamdar (Ref. 108) reported followup for 7 years on implantation of 193 Shiers design prostheses. They reported that 11 percent of the patients had aseptic loosening. Kaushal et al. (Ref. 109) reported followup examination of a series of 30 knees about 42 months following implantation of the prosthesis. The examination revealed that 13 knees (46 percent) had phlebothrombosis, 8 knees (11 percent) had asymptomatic loosening, 4 knees (5.4 percent) had deep infections, and 3 knees (4.3 percent) had symptomatic loosening. The major problems with use of the prosthesis were settling, loosening, and limitation on the range of joint motion allowed. In preliminary data, Van Camp et al. (Ref. 110) showed that stress loading appeared to cause mechanical loosening of the device.

Walker (Ref. 111) stated that the valgus angle of the knee was ignored in the older designs of this prosthesis. Walker said this design problem resulted in lateral stress on the intramedullary stems of the device. This theory was verified experimentally by Wagner and Bourgois (Ref. 112). Wagner and Bourgois also showed that, in both the Walldius and Shiers designs of the prosthesis, the prosthesis' axis of rotation was not equivalent to the axis of the anatomic joint it replaced. These researchers said the pin in the Shiers prosthesis was turned down on the axis and that it might loosen if the prosthesis were overstressed. Because the axle pin of the Walldius prosthesis is clamped on one side, the location of the axis causes localized wear.

Although infection immediately following implantation of a prosthesis is primarily a result of surgical technique, Swanson et al. (Ref. 113) stated that the design of the prosthesis may minimize the rate of infection associated with implantation. Swanson found that the infection rate was lower when less bone was removed for insertion of the device. Phillips and Taylor (Ref. 98) reported that most groups of patients who have received this prosthesis have suffered about a 10 percent higher incidence of infection than patients in whom other generic types of knee prostheses have been implanted.

In cases of total failure of implantation of a joint prosthesis, the prosthesis may be removed and the joint fused (arthrodesis). The rate of success in performing arthrodesis is related to the amount of bone that was removed to implant the device. Arthrodesis is difficult following implantation of a constrained joint replacement device.

(3) *Risks to health.*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Knee Joint Patellofemoral Polymer/Metal Semi-Constrained Cemented Prothesis (§ 888.3540)

(1) *Identification.* A knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace part of a knee joint in the treatment of primary patellofemoral arthritis or chondromalacia. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes a component made of alloys, such as cobalt-chromium-molybdenum or austenitic steel, for resurfacing the intercondylar groove (femoral sulcus) on the anterior aspect of the distal femur, and a patellar component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for use with bone cement (§ 888.3027). The patellar component is designed to be implanted only with its femoral component.

(2) *Summary of data.* The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, similar devices and a presentation made to the Panel. Fox reported on his clinical experience with this generic type of device. Fox stated that patellofemoral joint replacement was performed in more than 60 knees, with the followup since 1974. He reported that he, as well as his patients, were pleased with the results.

Other than the presentation to the Panel made by Fox, FDA was not aware of any clinical data for this device. Moreover, because Fox provided no details regarding the device or its implantation procedure, FDA was not certain that the devices Fox implanted belong to this generic class.

(3) *Risks to health.*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution of wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Knee Joint Patellofemorotibial Polymer/Metal/Metal Constrained Cemented Prosthesis (§ 888.3550)

(1) *Identification.* A knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component, a tibial component, a cylindrical bolt and accompanying locking hardware that are all made of alloys, such as cobalt-chromium-molybdenum, and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. The retropatellar surfacing component may be attached to the resected patella either with a metallic screw or luting agent. All stemmed metallic components within this generic class are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(2) *Summary of data.* The Panel based its recommendation on the Panel members' knowledge of, and experience with, the device and a presentation made to the Panel. Pritchard and Fox described their experiences with various patellofemoral joint replacing devices including this generic type of device. Pritchard has implanted patellofemorotibial joint prostheses in at least 100 patients during the 3 years prior to the Panel meeting. Also, Fox reported that he has achieved good results in over 60 cases since 1974. In May 1962, Young (Ref. 116) reported on a series of 16 patients ranging in age from 31 to 70 years who had a Young design prosthesis implanted (2 were bilateral implantations). With a followup time between 9 and 61 months (median of 20 months), 7 of these 16 experienced a clinical failure (43.8 percent) with a mean time of about 9 months before prosthesis removal and arthrodesis (joint fusion). In a later report in 1971, Young (Ref. 120) stratified results by indication: At least 3 of 19 osteoarthritic knees were failures (15.8 percent incidence); at least 17 of 45 rheumatoid knees failed (37.8 percent incidence); of 4 replacements for giant-cell tumor, 2 failed (50 percent incidence); and at least 6 of 10 traumatic arthritic knees failed (60 percent incidence).

Young noted that nine knees examined sometime after initial implantation demonstrated darkening in tissue adjacent to metallic components. Young believed that the darkening of tissue was caused by tissue contamination from corrosion products. Young also believed that similar tissue darkening was noted by Girzadas et al. (Ref. 117). Young believed that the darkening was caused by the bolts used in his design that were made from a cobalt-based alloy, whereas the other components were made from a casting alloy. Young stated that, as a result of his survey of the clinical results for 85 physicians who had implanted the Young-design prosthesis, he was not optimistic about use of the hinged metal/metal knee prostheses and their future for replacement arthroplasty.

In 1973, Hanslik (Ref. 121) reported results of using the device in 50 patients (two bilaterally implanted), principally for the indication of stereoarthrosis. Minimum followup was not given, while maximum followup was possibly 4 years. The patients ranged in age from 56 to 76 years. At least four failures (8 percent) were associated with restricted gliding of the patellofemoral articulation: One of these was attributed to polymethylmethacrylate-induced bony necrosis. Hanslik used the Young (Ref. 116) design of prosthesis and had made major modifications in implantation technique as recommended by Friedebold and Radloff (Refs. 115, 118, and 120). Hanslik performed partial resection of the patella rather than total excision and used a polymethylmethacrylate luting agent to grout the medullary stems (presumably in addition to the cancellous bone screws recommended by Young). Friedebold and Radloff (Ref. 119) reported on use of the prosthesis in femorotibial replacement in 11 patients ranging in age from 50 to 80 years, with between 6 months and 5 years of followup. There were three failures (27.3 percent).

(3) *Risks to health.*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reactions—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surface of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Knee Joint Femoral (Hemi-Knee) Metallic Uncemented Prosthesis (§ 888.3570)

(1) *Identification.* A knee joint femoral (hemi-knee) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component with or without protuberance(s) for the enhancement of fixation and is limited to those prostheses intended for use without bone cement (§ 888.3027).

(2) *Summary of data.* FDA was concerned about both the severity of the clinical complications resulting from use of the device and the rate at which these complications occur. The agency

used the complication classification scheme developed by Fox (Ref. 122) and grouped complications by time periods following surgical implantation; immediate postoperative complications, within 2 weeks; short term, within 24 months; and long term, more than 24 months. Platt and Pepler reported in 1969 their clinical results on 55 patients who had this prosthesis implanted with up to 10 years followup (Ref. 123). Their reported incidence of complications ranged from: General—none reported; systemic—none reported; and remote—1 late (2 years postoperatively) paranoid schizophrenia (1.8 percent); and (4) local—at least 45 percent. The most frequent complication was immediate postoperative infection with a presumed incidence of 25.5 percent. The reoperation rate for this series of patients was reported as 20 out of 62 knees or 32.4 percent; assuming only 1 reoperation per patient, a 36.4 percent revision rate will result.

Aufranc and Jones et al. (Refs. 124 and 125) made extensive modifications to M. Smith-Peterson's original ''keeled'' femoral condylar mold (Ref. 126) and commenced a series of device implantations employing a noncemented stemmed implant in 1952. Clinical results on 64 patients with a minimum of 1-year followup showed that the incidence of complications were: Zero for general and remote categories; 3.1 percent for systemic (2 thrombophlebitic episodes); and a minimum of 25 percent for cumulated local complications. Matching Platt and Pepler's experience (Ref. 124), the most frequent complication observed was immediate postoperative infection with a presumed incidence of 20.3 percent. This series of patients, as of mid-1969, displayed a reoperation rate of 14 out of 79 knees (17.7 percent), assuming only 1 reoperation per patient. Considering this result, with their report of 16 clinical results rated at less than ''fair,'' the failure rate is calculated as 38 percent with an average followup time of 87 months. Aufranc and Jones (Ref. 124) noted that 6 of their initial 14 implantations were failures (42.9 percent) with a maximum followup of 5 years; apparently 10 more years of surgical experience reduced the overall failure rate by 5 percent, without altering the principal reported failure modes: Infection and ''poor'' clinical result.

Further review of available literature (Refs. 108 and 127 through 136), failed to disclose device experience that would significantly alter the trends described above.

(3) *Risks to health.*

- Loss or reduction of joint or limb function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in the loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.
- Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution of wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation.
- Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.
- Death—Death may result from lipoembolic sequelae or thromboembolic complications during or immediately following implantation.

Knee Joint Patellar (Hemi-Knee) Metallic Resurfacing Uncemented Prosthesis (§ 888.3580)

(1) *Identification.* A knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted to replace the retropatellar articular surface of the patellofemoral joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a retropatellar resurfacing component and an orthopedic screw to transfix the patellar remnant. This generic type of device is limited to those prostheses intended for use without bone cement (§ 888.3027). This device is in class III when intended for uses other than treatment of degenerative and posttraumatic patellar arthritis; when intended for those uses, it is in class II.

(2) *Summary of data.* FDA was not aware of any valid scientific evidence supporting the safety and effectiveness of this device when intended for uses other than the treatment of degenerative and posttraumatic patellar arthritis.

3. *Risks to health.*

- Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.
- Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.
- Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Shoulder Joint Metal/Metal or Metal/Polymer Constrained Cemented Prosthesis (§ 888.3640)

(1) *Identification.* A shoulder joint metal/metal or metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid component made of this alloy or a combination of this alloy and ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(2) *Summary of data.* The Panel based its recommendation on the Panel members' personal knowledge of the device and on their knowledge of the medical literature (Refs. 136 through 139). Two of these references (Refs. 136 and 137) described a shoulder joint constrained prosthesis (Fenlin and Zippel designs) and report that implantation of the device relieved pain in 16 of 17 patients. In the patient with the painful prosthesis, the authors believed that the device had loosen. The times of implantation were not reported.

Fenlin (Ref. 138) reported that the Fenlin design prosthesis had been implanted in five patients. The results in three of these patients were discussed. One patient was described as being free of pain, and able to use the operated shoulder for all normal activities, except those requiring elevation of the arm above 80°. The length of followup in this patient was 20 months. Complications were reported in the other two patients. In one patient, the device had loosened at 3 months postoperatively, due to abnormal anatomy of the glenoid. The second patient suffered partial nerve palsy due to damage of the axillary nerve during surgery. Linscheid and Cofield (Ref. 139) reported on the implantation of 13 constrained shoulder joint prostheses (6

of the Stanmore design, and 7 of the Bickel design). The average time of followup was reported as 13 months and ranged from 2 to 26 months. There were two cases of dislocations of the Stanmore design prosthesis and one case of dislocation of the Bickel design prosthesis. There were two additional complications reported with the Bickel design device; one case of fracture of the humeral component and one case of loosening of the glenoid component.

FDA sought additional information on the safety and effectiveness of these devices. Cofield (Ref. 140) reported that prosthetic replacement of the shoulder joint was in 1971, an experimental, investigational procedure. This author noted that basic knowledge about shoulder biomechanics was limited and that current knowledge of shoulder prostheses was not sufficient to establish the requirements of a prosthetic replacement. Buechel et al. (Ref. 141) noted that complications with current shoulder prostheses have been associated with the designs of the devices: (1) The Bickel design shoulder joint prosthesis was reported to dislocate and loosen due to the limited motion of the prosthesis; and (2) the prosthesis design used by Lettin and Scales (presumably the Stanmore design shoulder prosthesis) was reported to significantly limit joint motion, then sublux, and eventually dislocate at the extremes of normal joint motion. Clinical results with several prosthesis designs were reported by Cofield (Ref. 140, 142, and 143). Eleven persons in whom Bickel design prostheses had been implanted were evaluated 18 months to 39 months postoperatively (Ref. 142). Three (27 percent) were experiencing significant pain. The components of the Bickel device had dislocated in two cases. The glenoid component had dislodged from the scapula in two cases and loosened in one. The humeral component had fractured in two other cases. Reoperation was required in four patients and was needed in two or three others. Cofield reported that further clinical and mechanical deterioration in these patients was anticipated due to progressive loosening of the glenoid components and fatigue fracture of the neck of the humeral component, which was not believed to be strong enough. These authors concluded that this type of shoulder joint replacement (i.e., the Bickel design) is not justified. Cofield (Refs. 140 and 143) also reported clinical results in nine patients who had received Stanmore prostheses. After an average postoperative time of 1 year (ranging between 4 and 18 months), six patients had satisfactory relief of pain and three had significant pain. The glenoid component had loosened in two patients. FDA concurred with the Panel that the reported clinical experience with these devices did not establish their long-term safety and effectiveness.

(3) *Risks to health.*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Shoulder Joint Glenoid (Hemi-Shoulder) Metallic Cemented (§ 888.3680) Prosthesis

(1) *Identification.* A shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis is a device that has a glenoid (socket) component made of alloys, such as cobalt-chromium-molybdenum, or alloys with ultra-high molecular weight polyethylene and intended to be implanted to replace part of a shoulder joint. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(2) *Summary of the data.* The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

(3) *Risks to health.*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

Wrist Joint Metal Constrained Cemented Prosthesis (§ 888.3790)

(1) *Identification.* A wrist joint metal constrained cemented prosthesis is a device intended to be implanted to replace a wrist joint. The device prevents dislocation in more than one anatomic plane and consists of either a single flexible across-the-joint component or two components linked together. This generic type of device is limited to a device which is made of alloys, such as cobalt-chromium-molybdenum, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(2) *Summary of data.* The Panel based its recommendation on the Panel members' personal knowledge of the device and on the available medical literature. Gschwend et al. (Ref. 144) used this prosthesis in 15 cases from 1971 through 1975. Fixation was reported to be inadequate and not correlated to loads imposed on the wrist joint. In three cases (20 percent), the distal stem became loose. The stem fractured in two cases (13 percent). On one occasion (6.6 percent) the metacarpal bone broke. In another case, as a result of a disturbance of muscle balance, the investigators observed a fixed ulnar deviation of the wrist joint with a tendency toward radial penetration of the medullary canal of the third metacarpal bone. The investigators also described three cases (20 percent) of a sinking of the prosthesis into the capitate through the third metacarpal.

(3) *Risks to health.*

• Loss or reduction of joint function—Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

• Adverse tissue reaction—Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and release of materials from the device to the surrounding tissues and systemic circulation.

• Infection—The presence of the prosthesis within the body may lead to an increased risk of infection.

10. Physical Medicine Devices

Rigid Pneumatic Structure Orthosis (§ 890.3610)

(1) *Identification*. A rigid pneumatic structure orthosis is a device intended for medical purposes to provide whole body support by means of a pressurized suit to help thoracic paraplegics walk.

(2) *Summary of data*. The Panel based its recommendation on the literature concerning the device (Refs. 145 and 146). The literature evaluation did not demonstrate that the device was safe or effective (Ref. 146). The rigid pneumatic structure orthosis was also evaluated as requested by the Veterans' Administration and the Rehabilitation Services Administration, Department of Health, Education, and Welfare (Ref. 146), and did not meet adequate performance standards for safety and effectiveness.

(3) *Risks to health*.

• Bodily injury—The device could collapse and the patient could fall, resulting in bodily injury, if inflation is lost or the zippers fail.

• Tissue trauma and/or pressure sores—Tissue trauma and/or pressure sores could result if the support beams overinflate and cause excessive pressure on the skin of the patient.

II. PMA Requirements

A PMA for these devices must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks identified above, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA should include valid scientific evidence obtained from well-controlled clinical studies, with detailed data, in order to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Applicants should submit any PMA in accordance with FDA's ''Premarket Approval (PMA) Manual.'' This manual is available upon request from FDA, Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850.

III. Request for Comments with Data

Interested persons may, on or before January 5, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. Opportunity to Request a Change in Classification

Before requiring the filing of a PMA or a notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the act and § 860.132 (21 CFR 860.132) to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of these devices is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by September 22, 1995.

The agency advises that, to ensure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of these devices is submitted, the agency will, by November 6, 1995, after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and § 860.130 (21 CFR 860.130) of the regulations.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because FDA believes that there is little or no interest in marketing these devices, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects

21 CFR Part 864

Blood, Medical devices, Packaging and containers.

21 CFR Parts 868, 870, 872, 876, 880, 882, 884, 888, and 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 864, 868, 870, 872, 876, 880, 882, 884, 888, and 890 be amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 864.5220 is amended by revising paragraph (c) to read as follows:

§ 864.5220 Automated differential cell counter.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule based on this proposed rule). For any automated differential cell counter described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule based on this proposed rule), been found to be substantially equivalent to an automated differential cell counter described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other automated differential cell counter described in paragraph (b)(2) of this section shall have an approved PMA or declared

completed PDP in effect before being placed in commercial distribution.

PART 868—ANESTHESIOLOGY DEVICES

3. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

4. Section 868.5400 is amended by revising paragraph (c) to read as follows:

§ 868.5400 Electroanesthesia apparatus.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule based on this proposed rule) for any electroanesthesia apparatus that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a electroanesthesia apparatus that was in commercial distribution before May 28, 1976. Any other electroanesthesia apparatus shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART—870 CARDIOVASCULAR DEVICES

5. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

6. Section 870.1350 is amended by revising paragraph (c) to read as follows:

§ 870.1350 Catheter balloon repair kit.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule). For any catheter balloon repair kit that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a catheter balloon repair kit that was in commercial distribution before May 28, 1976. Any other catheter balloon repair kit shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

7. Section 870.1360 is amended by revising paragraph (c) to read as follows:

§ 870.1360 Trace microsphere.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule). For any trace microsphere that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a trace microsphere that was in commercial distribution before May 28, 1976. Any other trace microsphere shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

8. Section 870.3850 is amended by revising paragraph (c) to read as follows:

§ 870.3850 Carotid sinus nerve stimulator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976. Any other carotid sinus nerve stimulator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

9. Section 870.5300 is amended by revising paragraph (c) to read as follows:

§ 870.5300 DC-defibrillator (including paddles).

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule). For any DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976. Any other DC-defibrillator (including paddles) described in paragraph (b)(1) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 872—DENTAL DEVICES

10. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

11. Section 872.3400 is amended by revising paragraph (c) to read as follows:

§ 872.3400 Karaya and sodium borate with or without acacia denture adhesive.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any karaya and sodium borate with or without acacia denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a karaya and sodium borate with or without acacia denture adhesive that was in commercial distribution before May 28, 1976. Any other karaya and sodium borate with or without acacia denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

12. Section 872.3420 is amended by revising paragraph (c) to read as follows:

§ 872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive that was in

commercial distribution before May 28, 1976. Any other carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

13. Section 872.3480 is amended by revising paragraph (c) to read as follows:

§ 872.3480 Polyacrylamide polymer (modified cationic) denture adhesive.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any polyacrylamide polymer (modified cationic) denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a polyacrylamide polymer (modified cationic) denture adhesive that was in commercial distribution before May 28, 1976. Any other polyacrylamide polymer (modified cationic) denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

14. Section 872.3500 is amended by revising paragraph (c) to read as follows:

§ 872.3500 Polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive that was in commercial distribution before May 28, 1976. Any other polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

15. Section 872.3560 is amended by revising paragraph (c) to read as follows:

§ 872.3560 OTC denture reliner.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any OTC denture reliner that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to an OTC denture reliner that was in commercial distribution before May 28, 1976. Any other OTC denture reliner shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

16. Section 872.3820 is amended by revising paragraph (c) to read as follows:

§ 872.3820 Root canal filling resin.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any root canal filling resin described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a root canal filling resin described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other root canal filling resin shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

17. The authority citation for 21 CFR part 876 is revised to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

18. Section 876.5220 is amended by revising paragraph (c) to read as follows:

§ 876.5220 Colonic irrigation system.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other colonic irrigation system shall have an approved PMA in effect before being placed in commercial distribution.

19. Section 876.5270 is amended by revising paragraph (c) to read as follows:

§ 876.5270 Implanted electrical urinary continence device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any implanted electrical urinary continence device that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to an implanted electrical urinary continence device that was in commercial distribution before May 28, 1976. Any other implanted electrical urinary continence device shall have an approved PMA or a declared completed PDP in effect before being place in commercial distribution.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

20. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

21. Section 880.5760 is amended by revising paragraph (c) to read as follows:

§ 880.5760 Chemical cold pack snakebite kit.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any chemical cold pack snakebite kit that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date

of publication of the final rule), been found to be substantially equivalent to a chemical cold pack snakebite kit that was in commercial distribution before May 28, 1976. Any other chemical cold pack snakebite kit shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 882—NEUROLOGICAL DEVICES

22. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

23. Section 882.1825 is amended by revising paragraph (c) to read as follows:

§ 882.1825 Rheoencephalograph.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any rheoencephalograph that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a rheoencephalograph that was in commercial distribution before May 28, 1976. Any other rheoencephalograph shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

24. Section 882.5150 is amended by revising paragraph (c) to read as follows:

§ 882.5150 Intravascular occluding catheter.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any intravascular occluding catheter that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a intravascular occluding catheter that was in commercial distribution before May 28, 1976. Any other intravascular occluding catheter shall have an approved PMA or a declared completed PDP in effect before being place in commercial distribution.

25. Section 882.5850 is amended by revising paragraph (c) to read as follows:

§ 882.5850 Implanted spinal cord stimulator for bladder evacuation.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any implanted spinal cord stimulator for bladder evacuation that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to an implanted spinal cord stimulator for bladder evacuation that was in commercial distribution before May 28, 1976. Any other implanted spinal cord stimulator for bladder evacuation shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

26. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

27. Section 884.2050 is amended by revising paragraph (c) to read as follows:

§ 884.2050 Obstetric data analyzer.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any obstetric data analyzer that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to an obstetrical data analyzer that was in commercial distribution before May 28, 1976. Any other obstetric data analyzer shall have an approved PMA or a declared completed PDP in effect before being place in commercial distribution.

28. Section 884.2620 is amended by revising paragraph (c) to read as follows:

§ 884.2620 Fetal electroencephalographic monitor.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any fetal electroencephalographic monitor that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a fetal electroencephalographic monitor in commercial distribution before May 28, 1976. Any other fetal electroencephalographic monitor shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

29. Section 884.2685 is amended by revising paragraph (c) to read as follows:

§ 884.2685 Fetal scalp clip electrode and applicator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any fetal scalp clip electrode and applicator that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a fetal scalp clip electrode and applicator that was in commercial distribution before May 28, 1976. Any other fetal scalp clip electrode and applicator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

30. Section 884.4250 is amended by revising paragraph (c) to read as follows:

§ 884.4250 Expandable cervical dilator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any expandable cervical dilator that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to an expandable cervical dilator that was in commercial distribution before May 28, 1976. Any other expandable cervical dilator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

31. Section 884.4270 is amended by revising paragraph (c) to read as follows:

§ 884.4270 Vibratory cervical dilators.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any vibratory cervical dilator that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a vibratory cervical dilator that was in commercial distribution before May 28, 1976. Any other vibratory cervical dilator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

32. Section 884.5050 is amended by revising paragraph (c) to read as follows:

§ 884.5050 Metreurynter-balloon abortion system.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any metreurynter-balloon abortion system that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a metreurynter-balloon abortion system that was in commercial distribution before May 28, 1976. Any other metreurynter-balloon abortion system shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

33. Section 884.5225 is amended by revising paragraph (c) to read as follows:

§ 884.5225 Abdominal decompression chamber.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any abdominal decompression chamber that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to an abdominal decompression chamber that was in commercial distribution before May 28, 1976. Any other abdominal decompression chamber shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 888—ORTHOPEDIC DEVICES

34. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

35. Section 888.3120 is amended by revising paragraph (c) to read as follows:

§ 888.3120 Ankle joint metal/polymer non-constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any ankle joint metal/polymer non-constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a ankle joint metal/polymer non-constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other ankle joint metal/polymer non-constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

36. Section 888.3180 is amended by revising paragraph (c) to read as follows:

§ 888.3180 Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any elbow joint humeral (hemi-elbow) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a elbow joint humeral (hemi-elbow) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other elbow joint humeral (hemi-elbow) metallic uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

37. Section 888.3200 is amended by revising paragraph (c) to read as follows:

§ 888.3200 Finger joint metal/metal constrained uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule), for any finger joint metal/metal constrained uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a finger joint metal/metal constrained uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other finger joint metal/metal constrained uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

38. Section 888.3210 is amended by revising paragraph (c) to read as follows:

§ 888.3210 Finger joint metal/metal constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any finger joint metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a finger joint metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other finger joint metal/metal constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

39. Section 888.3220 is amended by revising paragraph (c) to read as follows:

§ 888.3220 Finger joint metal/polymer constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90

days after date of publication of the final rule) for any finger joint metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a finger joint metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other finger joint metal/polymer constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

40. Section 888.3300 is amended by revising paragraph (c) to read as follows:

§ 888.3300 Hip joint metal constrained cemented or uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any hip joint metal constrained cemented or uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a hip joint metal constrained cemented or uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal constrained cemented or uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

41. Section 888.3310 is amended by revising paragraph (c) to read as follows:

§ 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any hip joint metal/polymer constrained cemented or uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a hip joint metal/polymer constrained cemented or uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal/polymer constrained cemented or uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

42. Section 888.3370 is amended by revising paragraph (c) to read as follows:

§ 888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any hip joint (hemi-hip) acetabular metal cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a hip joint (hemi-hip) acetabular metal cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal (hemi-hip) acetabular metal cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

43. Section 888.3380 is amended by revising paragraph (c) to read as follows:

§ 888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

44. Section 888.3480 is amended by revising paragraph (c) to read as follows:

§ 888.3480 Knee joint femorotibial metallic constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any knee joint femorotibial metallic constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication in the **Federal Register** of the final rule based on this proposed rule), been found to be substantially equivalent to a knee joint femorotibial metallic constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint femorotibial metallic constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

45. Section 888.3540 is amended by revising paragraph (c) to read as follows:

§ 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.

* * * * *

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

46. Section 888.3550 is amended by revising paragraph (c) to read as follows:

§ 888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis

that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

47. Section 888.3570 is amended by revising paragraph (c) to read as follows:

§ 888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any knee joint femoral (hemi-knee) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a knee joint femoral (hemi-knee) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint femoral (hemi-knee) metallic uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

48. Section 888.3580 is amended by revising paragraph (c) to read as follows:

§ 888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

49. Section 888.3640 is amended by revising paragraph (c) to read as follows:

§ 888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any shoulder joint metal/metal or metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a shoulder joint metal/metal or metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other shoulder joint metal/metal or metal/polymer constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

50. Section 888.3680 is amended by revising paragraph (c) to read as follows:

§ 888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis that was in commercial distribution before May 28, 1976. Any other shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

51. Section 888.3790 is amended by revising paragraph (c) to read as follows:

§ 888.3790 Wrist joint metal constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any wrist joint metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a wrist joint metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other wrist joint metal constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 890—PHYSICAL MEDICINE DEVICES

52. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

53. Section 890.3610 is amended by revising paragraph (c) to read as follows:

§ 890.3610 Rigid pneumatic structure orthosis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule) for any rigid pneumatic structure orthosis that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule), been found to be substantially equivalent to a rigid pneumatic structure orthosis that was in commercial distribution before May 28, 1976. Any other rigid pneumatic structure orthosis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: August 9, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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