Proposed Rules

Federal Register
Vol. 67, No. 26
Thursday, February 7, 2002

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 01N–0339]

Medical Devices; Proposed Classification for Medical Washer and Medical Washer-Disinfector

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the medical washer and medical washer-disinfector intended for general medical purposes to clean and dry surgical instruments, decontaminate or disinfect anesthesia equipment, hollowware, and other medical devices into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that FDA intends to use as the special control for these devices. After considering public comments on the proposed classification, FDA will publish a final regulation classifying these devices. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices.

DATES: Submit written or electronic comments by May 8, 2002. See section VII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301– 443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food Drug Administration Modernization Act of 1997 (the FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures (510(k)), without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Consistent with the act and the regulations, FDA consulted with the General Hospital and Personal Use Devices Panel (the Panel), an FDA advisory committee regarding the classification of the medical washers and medical washer-disinfectors.

Medical washers intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices, and medical washer-disinfectors intended additionally to decontaminate or disinfect medical devices were in commercial distribution prior to May 28, 1976, the date of the Medical Device Amendment to the act. Medical washers and medical washer-disinfectors are considered medical devices within the meaning of section 201(h) of the act (21 U.S.C. 321(h)). Although they were legally marketed medical devices, the medical washers and medical washer-disinfectors were not included among the devices that were classified in 1980 by the Panel. Because the medical washers and medical washer-disinfectors are not dedicated to a single type of device, FDA has not considered them as accessories to classified medical devices. Although FDA has classified several generic types of washers and washer-disinfectors by regulation, medical washers and medical washer-disinfectors intended for general medical purposes to reprocess a variety of devices have not been classified by regulation and are therefore considered as unclassified devices.

Prior to June 1998, it was unclear to regulated industry whether the unclassified medical washers and medical washer-disinfectors were devices subject to the 510(k) requirements of the act. On June 2, 1998, FDA published on the Center for Devices and Radiological Health (CDRH)

Internet site the document entitled ''Guidance Document for Washers and Washer-Disinfectors Intended for Processing Medical Devices,'' which clarified their regulatory status at that time. FDA informed industry that these devices were subject to the 510(k) requirements of the act; that FDA would have a Panel meeting for the purpose of classifying these devices; and that FDA would provide guidance on the types of information to be included in a submission. The Panel was convened on September 14, 1998. In the **Federal Register** of November 5, 1998 (63 FR 59794), FDA announced the availability of the draft guidance and invited interested persons to comment on the guidance.

FDA has classified the following generic types of washers and washer-disinfectors that were in commercial distribution prior to May 28, 1976, by regulation. Washers and washer-disinfectors intended to process only ''general purpose articles,'' such as laboratory glassware, pipettes, bottles, and containers, although considered as medical devices, are treated by FDA as ''general purpose'' articles exempt from registration under § 807.65(c) and from the 510(k) requirements of the act.

Washers labeled only to wash and sanitize body waste receptacles, such as bedpans, have been classified as class I devices under 21 CFR 880.6800 (washers for body waste receptacles) and are exempt from the 510(k) requirements of the act (subject to the limitations on exemptions found in § 880.9 (21 CFR 880.9)).

Ultrasonic cleaners, which are intended to clean medical instruments by emission of high frequency soundwaves, and any cleaning solution intended for use with the ultrasonic cleaners, have been classified as class I devices under 21 CFR 880.6150 and are exempt from 510(k) requirements of the act (subject to the limitations on exemptions found in § 880.9).

Products used in the cleaning and disinfection of rigid gas permeable and soft (hydrophilic) contact lenses are classified as class II devices under 21 CFR 886.5918 and 886.5925, respectively.

FDA considers washers, washer-disinfectors, or disinfectors intended solely for the processing of flexible endoscopes as accessories to endoscopes. Under the definition of a medical device, an accessory to a medical device is itself considered a medical device and is regulated in the same class as the associated medical device. Therefore, endoscope washers, endoscope washer-disinfectors, or endoscope disinfectors are considered in the same class as endoscopes under 21 CFR 876.1500. Endoscopes and accessories are class II devices.

II. Recommendation of the Panel

During a public meeting, which was held on September 14, 1998, the Panel made the following recommendation regarding the classification of the general use washers and washer-disinfector. ''General use'' was the identifying terminology used at the time of Panel deliberations.

A. Identification

The Panel recommended that the device be identified as follows: A general use washer or washer-disinfector is a device intended for medical purposes to clean, decontaminate or disinfect, and dry surgical instruments, anesthesia equipment, hollowware and other medical devices. A general use washer or washer-disinfector can be equipped with electromechanical control systems or with microprocessor control systems and may have one or more cleaning and decontamination/disinfection cycles for a variety of medical devices. The device can be a free standing, single or double door unit or a wall recessed, pass-through unit with spray arms, nozzles, and adapters for directing fluid flow onto the external and internal surfaces of the medical devices. It may also have accessory inserts, such as specialized trays and racks, for processing a wide variety of instruments. The washer or washer-disinfector may clean, decontaminate or disinfect, and dry medical devices using preset cycles with defined-contact parameters. The cleaning phase may automatically dilute and dispense the cleaning agent or may require the user to dilute and add the cleaning agent manually. In some instances, manual precleaning of patient exposed devices may be necessary before placing them in the general use washer or washer-disinfector because of complex device designs or because of heavy soiling of the medical devices. The disinfection phase may be either a thermal process using heated water or steam or a chemical process using a liquid chemical germicide.

B. Recommended Classification of the Panel

The Panel unanimously recommended that the general use washer and washer-disinfector be classified into class II. The Panel believed that special controls in addition to the general controls would provide reasonable assurance of the safety and effectiveness of the device. The Panel recommended the following as special controls: FDA guidance, voluntary consensus standards, and user information/education.

C. Summary of Reasons for Recommendation

The Panel considered the information provided by FDA and industry, open discussions during the Panel meeting, and their clinical experience with the device in making their recommendation. The Panel then voted that general use washers and washer-disinfectors that are intended for medical purposes to clean, decontaminate or disinfect, and dry medical devices should be classified into class II. The Panel believed that special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and that there was sufficient information to establish special controls to provide such assurance.

D. Summary of Data Upon Which the Recommendation is Based

The Panel discussed a proposal to classify the general use washers and washer-disinfectors according to their intended use into two classes. Devices with cleaning as the only intended use would be placed in class I, whereas devices that are intended to be used for both cleaning and disinfection would be placed in class II. The Panel, however, noted that most of these devices would be placed in central services departments of healthcare facilities and believed that the majority of the devices would be intended for use as a washer-disinfector system rather than for use as a washer. The Panel recognized that a wide variety of medical devices, such as surgical instruments, anesthesia equipment, hollowware, and many other medical devices, are processed in these general use washers and washer-disinfectors and it is extremely difficult to dissociate the cleaning process from the disinfection process. Consequently, the Panel rejected the option of classifying the device intended only for washing as a class I device. The Panel recommended that the general use washers and washer-disinfectors, whether intended only for cleaning or intended for both cleaning and disinfection, be classified as class II.

The Panel acknowledged that those washers and washer-disinfectors already classified by regulation, such as washers for body waste receptacles, washers for general purpose articles, such as laboratory glassware, ultrasonic cleaners, washers and washer-disinfectors for flexible endoscopes, and contact lens cleaners, would not be affected by this classification.

E. Risks to Health

The Panel identified the following risks associated with the use of these devices: (1) Potential for increased risk of nosocomial infections; if general use washers and washer-disinfectors fail to process medical devices adequately, the medical device may serve as a potential vector for infection; (2) damage to medical devices if the cycle parameters or the liquid chemical germicide are incompatible with the medical device; damaged devices may fail to function or have areas that cannot be reprocessed effectively; (3) exposure of patient and healthcare users to chemical residues; if a liquid chemical germicide is used during the disinfection step, healthcare users and patients can be exposed to toxic residues if the rinse cycles are inadequate; (4) healthcare user exposure to toxic fumes from liquid chemical germicides or burns caused by exposure to hot water/steam used in the disinfection step; (5) electrical hazards; (6) electro-magnetic interference with the electronic components resulting in firmware failures; and (7) software failures.

F. Special Controls

In the **Federal Register** of November 5, 1998 (63 FR 59794), FDA announced the availability of the draft guidance document entitled ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer-Disinfectors.'' The draft guidance outlines the recommended testing to support the intended use of these devices. It recommends physical performance testing demonstrating that the general use washers and washer-disinfectors meet and maintain parameter specifications for each cycle. The draft guidance also provides information on the types of microbicidal performance testing to support the intended level of disinfection. In addition, it contains recommendations for residue testing, software documentation, and electrical and electromagnetic compatibility. The guidance includes recommendations on the types of information that should be included in the labeling for the general use washers and washer-disinfectors to provide the user with sufficient information for the proper use of these devices. FDA reviewed the comments on the draft guidance and has revised the guidance. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that FDA intends to use as the special control for these devices (the special control guidance document).

Although the Panel recommended voluntary consensus standards as a special control when classifying the ''general use'' washers and washer-disinfectors, as they were termed at the time of Panel deliberations, there are currently no voluntary consensus design or performance standards specific to the ''general use'' washers and washer-disinfectors. There are more general applicable voluntary consensus standards, e.g., electrical safety standards. In the future, when voluntary standards are adopted for ''general use'' washers and washer-disinfectors, they can be incorporated in the FDA special control guidance document.

User information and education is critical to ensure that the users have full knowledge and can assume responsibility for the safe and effective use of the general use washers and washer-disinfectors. The Panel recommended user information and education as a special control. The FDA special control guidance document describes the type of information that should be made available to users of the ''general use'' washers and washer-disinfectors. The special control guidance document can be amended as the information and educational needs are updated.

III. Proposed Classification

FDA believes that in order to reduce the potential for confusion, the identification terms ''general use'' washer and ''general use washer-disinfector'' as recommended by the Panel should be changed to ''medical washer'' and ''medical washer-disinfector.'' The new terms will distinguish these devices from ''general purpose article'' washers and washer-disinfectors that are exempt from 510(k) requirements. FDA also believes that decontamination and disinfection are distinct intended uses that require FDA to distinguish washers from washer-disinfectors in classification descriptions.

FDA concurs with the Panel that the medical washers and washer-disinfectors should be classified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

As the Panel initially considered, FDA believes that the medical washer can be exempt from 510(k) requirements and that some medical washer-disinfectors can also be exempted from 510(k) requirements depending on intended use. The medical washer-disinfector intended to clean and high level disinfect medical devices should be subject to 510(k) requirements because the reusable devices subject to a high level disinfection process may pose a high risk of infection and other serious sequelae if the washer-disinfector is unsafe or ineffective. The medical washer-disinfector intended to clean and provide low or intermediate level disinfection can be exempt from 510(k) requirements because the reusable devices subject to low or intermediate disinfection pose a relatively lower risk of infection and other serious sequelae if the washer-disinfector is unsafe or ineffective.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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. Manufacturers of these devices are already subject to 510(k) requirements. Some of these devices will now be exempt from the 510(k) requirement. The guidance will not add significantly to the information FDA presently requires in a 510(k). Therefore, FDA has determined that this proposed rule will impose little or no additional economic impact on any

small entities. The agency therefore certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under to section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Submission of Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this proposal by May 8, 2002. 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.

VII. Proposed Dates

FDA proposes that any final regulation based on this proposal become effective 30 days after its publication in the **Federal Register**.

VIII. References

The following reference 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.

1. Transcript of General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee Meeting, September 14, 1998.

List of Subjects in 21 CFR Part 880

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 part 880 be amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

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

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Sections 880.6991 and 880.6992 are added to subpart G to read as follows:

§ 880.6991 Medical washer.

(a) *Identification.* A medical washer is a device that is intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware and other medical devices.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors.'' The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

§ 880.6992 Medical washer-disinfector.

(a) *Identification.* A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors.'' Medical washer-disinfectors that are intended only to clean, and provide low or intermediate level disinfection and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

Dated: August 24, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–3019 Filed 2–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 01N–0411]

Orthopedic Devices; Proposed Classification for the Resorbable Calcium Salt Bone Void Filler Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the resorbable calcium salt bone void filler device intended to fill bony voids or gaps, caused by trauma or surgery, that are not intrinsic to the stability of the bony structure into class II (special controls). The agency is also publishing the recommendation of the Orthopedic and Rehabilitation Devices Panel (the Panel) regarding the classification of this device. After considering public comments on the proposed classification, FDA will publish a final regulation classifying this device. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that the agency proposes to use as a special control for the device.

DATES: Submit written or electronic comments by May 8, 2002. See section XIII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Nadine Y. Sloan, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629) and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval). Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will ensure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance.

The SMDA broadened the definition of class II devices to mean those devices for which there is insufficient