Dated: September 28, 2000.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 00–25965 Filed 10–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 98N–0753]

Dental Products Devices; Reclassification of Endosseous Dental Implant Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the manually powered drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics, trial abutments, and other manually powered endosseous dental implant accessories from class III to class I. These devices are intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than an hour. FDA is also exempting these devices from premarket notification. This reclassification is on the Secretary of Health and Human Services' own initiative based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This rule is effective November 9, 2000.

FOR FURTHER INFORMATION CONTACT: Angela Blackwell, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and 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 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 section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under 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 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, 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.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' on which any reclassification is based is required to consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), *cert. denied*, 474 U.S. 1062 (1985). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

FDAMA added a new section 510(l) to the act. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. Hereafter, these are referred to as ''reserved criteria.'' FDA has considered the endosseous dental implant accessories in accordance with the reserved criteria and determined that

the devices do not require premarket notification. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA.

II. Regulatory History of the Device

In the **Federal Register** of October 7, 1998 (63 FR 53859), FDA proposed to reclassify the manually powered drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics, trial abutments, and other manually powered endosseous dental implant accessories from class III to class I. These devices are intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. Interested persons were given until January 5, 1999, to comment on the proposed regulation. FDA received no comments on the proposed rule.

III. Summary of Final Rule

FDA is reclassifying the manually powered drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics, trial abutments, and other manually powered endosseous dental implant accessories from class III to class I. These devices are intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices do not have a history of risks associated with them. FDA believes that the manufacturers' adherence to current good manufacturing practices in the quality system regulation will provide reasonable assurance of the safety and effectiveness of these devices. FDA, therefore, believes that class I would provide reasonable assurance of safety and effectiveness. FDA is also exempting the devices from the premarket notification requirements.

Therefore, under section 513 of the act, FDA is adopting the assessment of the risks to public health stated in the proposed rule published on October 7, 1998. Furthermore, FDA is issuing a final rule that revises part 872 (21 CFR part 872) in subpart D to add § 872.3980, thereby reclassifying the endosseous dental implant accessories, from class III into class I.

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 final 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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 the final rule reclassifying these devices from class III to class I will relieve all manufacturers of the devices of the cost of complying with the premarket approval requirements in section 513 of the act, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that the final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final 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 of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 in subpart D is amended as follows:

PART 872—DENTAL DEVICES

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

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

2. Section 872.3980 is added to subpart D to read as follows:

§ 872.3980 Endosseous dental implant accessories.

(a) *Identification.* Endosseous dental implant accessories are manually powered devices intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices include drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics, and trial abutments.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

Dated: September 26, 2000.

Linda S. Kahan, Deputy Director for Regulations Policy center for Devices and Radiological Health.

[FR Doc. 00–25811 Filed 10–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

28 CFR Part 0

[AG Order No. 2328–2000]

Delegation of Authority: Settlement Authority

AGENCY: Department of Justice

ACTION: Final rule.

SUMMARY: This rule delegates to the directors and commissioners of specified components of the Department of Justice authority to settle administrative claims presented pursuant to the Federal Tort claims Act (FTCA), where the amount of the settlement does not exceed $50,000. Currently, the directors and commissioners of the Bureau of Prisons, Federal Prison Industries, Immigration and Naturalization Service, Marshals Service, and the Drug Enforcement Administration have authority to settle FTCA claims not exceeding $10,000. This rule will alert the general public to the new authority of these officials and is being codified in the Code of Federal Regulations to provide a permanent record of this delegation.

EFFECTIVE DATE: October 10, 2000.

FOR FURTHER INFORMATION CONTACT: Jeffrey Axelrad, Director, Torts Branch, Civil Division, U.S. Department of Justice, P.O. Box 888, Benjamin Franklin Station, Washington, DC 20044, (202) 616–4400.

SUPPLEMENTARY INFORMATION: This rule has been issued to delegate settlement authority to various Department of Justice officials. It is a matter solely related to the division of responsibility within the Department of Justice. It relates to matters of agency policy, management, or personnel, and is therefore exempt from the usual requirements of prior notice and comment, and a 30-day delay in the effective date. See 5 U.S.C. 553(a)(2), (b)(A).

Executive Order 12866

This rule falls within a category of actions that the Office of Management and Budget (OMB) has determined do not constitute ''significant regulatory actions'' under section 3(f) of Executive Order 12866 and, accordingly, was not reviewed by OMB.

Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, the Department of Justice has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this regulation and, by approving it, certifies that this regulation will not have a significant economic impact upon a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804.

This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Plain Language Instructions

We try to write clearly. If you can suggest how to improve the clarity of these regulations, call or write Jeffrey Axelrad at the address and telephone number given above.

List of Subjects in 28 CFR Part 0

Authority delegations (government agencies), Claims.

Accordingly, Part 0 of Title 28 of the Code of Federal Regulations is amended as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT

1. The authority citation for Part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

2. Section 0.172 of Part 0, Subpart Y, is amended by revising paragraph (a) to read as follows:

§ 0.172 Authority: Federal tort claims.

(a) The Director of the Bureau of Prisons, the Commissioner of Federal Prison Industries, the Commissioner of the Immigration and Naturalization Service, the Director of the United States Marshals Service, and the Administrator of the Drug Enforcement Administration shall have authority to adjust, determine, compromise, and settle a claim involving the Bureau of Prisons, Federal Prison Industries, the Immigration and Naturalization Service, the United States Marshals Service, and the Drug Enforcement Administration, respectively, under section 2672 of title 28, United States Code, relating to the administrative settlement of Federal tort claims, if the amount of a proposed adjustment, compromise, settlement, or award does not exceed $50,000. When, in the opinion of one of those officials, such a claim pending before him presents a novel question of law or a question of policy, he shall obtain the advice of the Assistant Attorney General in charge of the Civil Division before taking action on the claim.

* * * * *

Dated: October 2, 2000.

Janet Reno,

Attorney General.

[FR Doc. 00–25904 Filed 10–6–00; 8:45 am]

BILLING CODE 4410–12–M

SELECTIVE SERVICE SYSTEM

32 CFR Part 1615

Additional Methods of Selective Service Registration

AGENCY: Selective Service System (SSS).

ACTION: Final rule; technical amendment.

SUMMARY: In accordance with Proclamation 7275 of February 22, 2000, this Final Rule amends the Administration of Registration rules by providing additional methods of registering with the Selective Service System. Proclamation 7275 amended Proclamation 4771 to allow for additional methods of registration. These methods include registration on