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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 888**

Display Date 6-11-07  
Publication Date 6-12-07  
Certifier A. Corbin

**[Docket No. 2006N-0019]**

**Orthopedic Devices; Reclassification of the Intervertebral Body Fusion Device**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is reclassifying intervertebral body fusion devices that contain bone grafting material, from class III (premarket approval) into class II (special controls), and retain those that contain any therapeutic biologic (e.g., bone morphogenic protein) in class III. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for this device. This reclassification is based upon on the recommendation of the Orthopaedic and Rehabilitation Devices Panel (the Panel).

**EFFECTIVE DATE:** *[Insert date 30 days after date of publication in the **Federal Register**].*

**FOR FURTHER INFORMATION CONTACT:** Jodi N. Anderson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850, 240-276-3680.

**SUPPLEMENTARY INFORMATION:**

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## 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 (1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (Public Law 101–629), the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), and the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), 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 done the following: (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 before 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 the device is reclassified into class I or II or 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 part 807 (21 CFR part 807) of the regulations.

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

Section 513(e) of the act (21 U.S.C. 360c(e)) governs reclassification of classified preamendments devices. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon “new information.” FDA can initiate a reclassification under section 513(e) of the act or an interested person may petition FDA to reclassify a preamendments device. 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.) Whether data before the agency are past or new data, the “new information” to support reclassification under section 513(e) must be “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. To be considered in the reclassification process, 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).) Section 520(h)(4) of the act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

FDAMA added a new section 510(m) to the act. New section 510(m) of the act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the act, if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA believes that this device should not be exempt from premarket notification under section 510(m) of the act. FDA believes that

it needs to review information in a premarket notification submission that addresses the risks identified in the guidance document in order to assure that a new device is at least as safe and effective as legally marketed devices of this type.

## **II. Regulatory History of the Device**

In the **Federal Register** of February 9, 2006 (71 FR 6710), FDA published a proposed rule to reclassify the intervertebral body fusion devices that contain bone grafting material, from class III (premarket approval) into class II (special controls), and retain those that contain any therapeutic biologic (e.g., bone morphogenic protein) in class III. FDA received 12 comments on the proposed rule and draft guidance.

In the same issue of the **Federal Register** of February 9, 2006 (71 FR 6778), FDA announced the availability of the draft guidance document entitled "Class II Special Controls Guidance Document: Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" that FDA intended to serve as the special control for this device type, if FDA reclassified this device type. Interested persons were invited to comment on the proposed rule and special controls draft guidance document by May 10, 2006.

## **III. Summary of Final Rule**

Therefore, under sections 513 and 520(l) of the act, FDA is adopting the summary of reasons for the panel's recommendation, the summary of data upon which the panel's recommendations are based (Ref. 1), and the assessment of the risks to public health stated in the proposed rule published on February 9, 2006. Furthermore, FDA is issuing this final rule (21 CFR 888.3080), that reclassifies intervertebral body fusion devices that contain bone grafting material, from class III (premarket approval) into class II (special

controls), and retain those that contain any therapeutic biologic (e.g., bone morphogenic protein) in class III.

#### **IV. Analysis of Comments and FDA's Response**

FDA received six comments stating the comment's full support for the reclassification as proposed and offering no additional input. Two comments suggested adding thoracic use to the classification identification. FDA disagrees with this comment because there are no legally marketed intervertebral body fusion devices indicated for thoracic use, and thus there is no experience with thoracic use of the intervertebral body fusion device. Two comments suggested that FDA classify all intervertebral body fusion devices into class II regardless of the grafting material the devices contain and regardless of whether grafting materials composed of therapeutic biologics remain class III. FDA disagrees with this comment. The intervertebral body fusion device and the grafting material it contains do not act independently in the body, thus the mitigation measures described in the special controls guidance are insufficient to provide reasonable assurance of safety and effectiveness for an intervertebral body fusion device when it contains a therapeutic biologic grafting material. The two remaining comments pertained to scientific recommendations in the draft guidance. FDA's consideration of these two comments is discussed in the notice of the availability of the guidance, published elsewhere in this issue of the **Federal Register**.

#### **V. Environmental Impact**

The agency has determined under 21 CFR 25.34(b) that this reclassification 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 final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–602), 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 not a significant regulatory action 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. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the costs of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes an Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$122 million, using the most current (2005) Implicit

Price deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

## **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.

## **VIII. Paperwork Reduction Act of 1995**

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) is not required. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Devices." The notice contains the PRA analysis for the guidance.

## **IX. References**

The following reference has been placed on display in the division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Orthopedic and Rehabilitation Devices Panel Meeting Transcript, pp. 1–141, December 11, 2003.

## List of Subjects in 21 CFR Part 888

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 888 is amended as follows:

### PART 888—ORTHOPEDIC DEVICES

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

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

- 2. Section 888.3080 is added to subpart D to read as follows:

**§ 888.3080 Intervertebral body fusion device.**

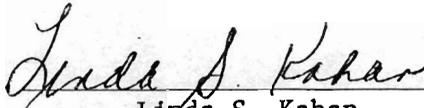
(a) *Identification.* An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.

(b) *Classification.* (1) Class II (special controls) for intervertebral body fusion devices that contain bone grafting material. The special control is the FDA guidance document entitled “Class II Special Controls Guidance Document: Intervertebral Body Fusion Device.” See § 888.1(e) for the availability of this guidance document.

(2) Class III (premarket approval) for intervertebral body fusion devices that include any therapeutic biologic (e.g., bone morphogenic protein). Intervertebral body fusion devices that contain any therapeutic biologic require premarket approval.

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: 5/31/07  
May 31, 2007.

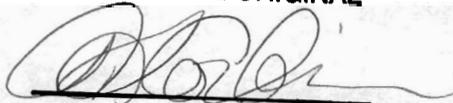
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Linda S. Kahan,  
Deputy Director,  
Center for Devices and Radiological Health.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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