

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

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Certifier A. Corbin

[Docket No. 01N-0411]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the resorbable calcium salt bone void filler device intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a class II special controls guidance entitled "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA." This action is being undertaken based on new information submitted in a classification proposal from Wright Medical Technology under the Federal Food, Drug, and Cosmetic Act as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997.

DATES: This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

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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. Background

In the **Federal Register** of February 7, 2002 (67 FR 5753), FDA issued a proposed rule to classify the resorbable calcium salt bone void filler device into class II based on new information regarding this device and on the recommendation of the Orthopedic and Rehabilitation Devices Panel. FDA identified the draft guidance document entitled “Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Draft Guidance for Industry and FDA” as the proposed special control capable of providing reasonable assurance of the safety and effectiveness of the device. The device is intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure. FDA invited interested persons to comment on the proposed rule by May 8, 2002. FDA received two comments, both supporting the proposed classification. One of the two comments also requested minor changes to the class II special controls guidance document.

II. Analysis of Comments and FDA’s Response

One comment expressed concern over a perceived intent to apply the guidance to demineralized bone matrix (DBM) products. FDA acknowledges that there was a misunderstanding about whether the proposed rule applied to DBM products that have the same intended use as the resorbable calcium salt bone void filler device and that were recently determined to be medical

devices. The proposed rule was intended to be specific to the resorbable calcium salt bone void filler device, including resorbable calcium salt bone void fillers that may contain some biologically sourced additives, including DBM. The proposed rule was not intended to apply to DBM products, i.e., products that contain DBM without any calcium salt or that are composed primarily of DBM. For clarity, FDA has deleted reference to all biologically sourced materials included in the proposed rule and draft class II special controls guidance and will address devices made of these other materials in the future.

III. FDA's Conclusion

Based on a review of the available information in the preamble to the proposed rule and placed on file in FDA's Dockets Management Branch, FDA concludes that special controls, in conjunction with general controls, provide reasonable assurance of the safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the class II special controls guidance document. The class II special controls guidance document was revised to reflect consideration of the comments received. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a resorbable calcium salt bone void filler device will need to address the issues covered in the class II special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA is now codifying the classification and the class II special control guidance document for the resorbable calcium salt bone void filler device by adding § 888.3045. For the convenience of the reader, FDA is also adding

§ 888.1(e) to inform the reader where to find guidance documents referenced in 21 CFR part 888.

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), 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 it 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. These devices are already subject to general controls, such as premarket notification. The class II special controls guidance document will not substantially change the way in which these devices are regulated. The agency, therefore, certifies that the final rule will not have a significant 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 is not required.

VI. 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 Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This final rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

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:

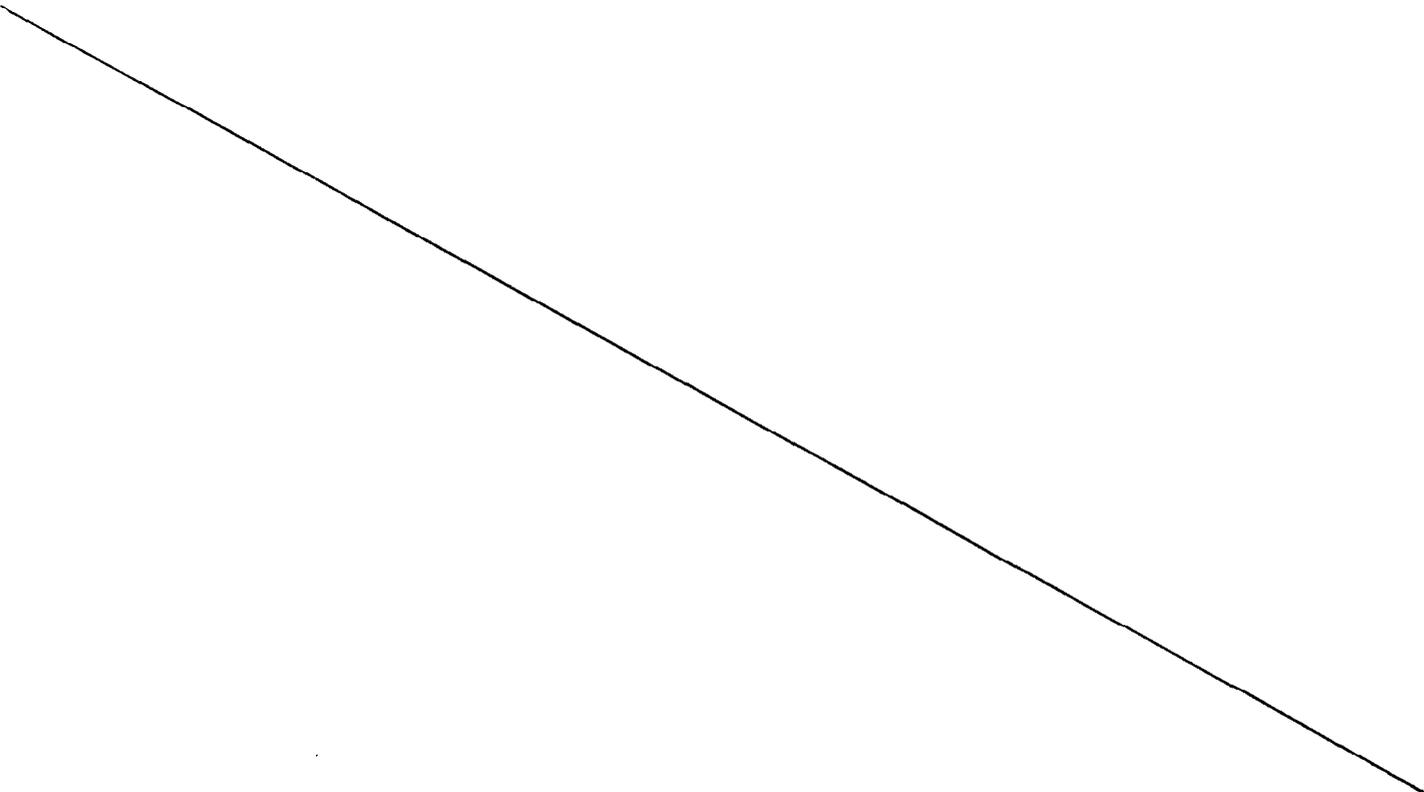
Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3045 is added to subpart D to read as follows:

§ 888.3045 Resorbable calcium salt bone void filler device.

(a) *Identification.* A resorbable calcium salt bone void filler device is a resorbable implant intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA.” See § 888.1(e) of this chapter for the availability of this guidance.



Dated: 7/9/03
April 9, 2003.

Linda S. Kahan

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

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