

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA-2005-N-<sup>0346</sup>~~0365~~] (formerly Docket No. 2005N-0467)

*JDM*  
Display Date 7-16-08  
Publication Date 7-17-08  
Certifier Spence

**Medical Devices; Radiology Devices; Reclassification of Bone Sonometers**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule to reclassify bone sonometer devices from class III into class II, subject to special controls. FDA is taking this action on its own initiative after reviewing recent scientific and technological studies regarding bone sonometer devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers" that will serve as the special control for these devices.

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

**FOR FURTHER INFORMATION CONTACT:** Robert A. Phillips, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3666.

**SUPPLEMENTARY INFORMATION:**

**I. Regulatory Authority**

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-

295), the Safe Medical Devices Act (SMDA) (Public Law 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), the Medical Devices Technical Corrections Act (MDTCA) (Public Law 108–214), and the Food and Drug Administration Amendments Act (FDAAA), establishes 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 type; and (3) published a final regulation classifying the device type. 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 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 predicate 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.

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.

Section 513(f)(3) of the act allows FDA to initiate reclassification of a postamendment device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device to petition the Secretary of the Department of Health and Human Services for the issuance of an order classifying the device in class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such class III devices. To change the classification of the device, it is necessary that the proposed new classification have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

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

In the **Federal Register** of February 15, 2006 (71 FR 7894), FDA published a proposed rule to reclassify bone sonometers from class III (premarket approval) into class II (special controls) after reviewing current technological and scientific developments. Specifically, the Center for Devices and Radiological Health (CDRH) reviewed recent studies addressing performance characteristics of bone sonometers manufactured by different companies and determined that, when combined with mitigation measures to offset the risks

of use associated with these devices, special controls would be adequate to assure the safety and effectiveness of bone sonometers. Interested persons were invited to comment on the proposed rule by May 16, 2006. FDA also identified the draft guidance document entitled “Draft Guidance for Industry and FDA Staff; Class II Special Controls Draft Guidance Document; Bone Sonometers” as the proposed special control capable of providing reasonable assurance of safety and effectiveness for these devices (71 FR 7976).

### **III. Analysis of Comments and FDA’s Response**

FDA received a number of comments on the proposed rule and draft guidance document. Each of the comments supported the reclassification of bone sonometers from class III into class II, but made specific suggestions with regard to the general scope and clinical testing sections of the guidance. FDA agreed with the following suggested changes to the special controls guidance and revised the document accordingly: (1) Determining device-specific T-score thresholds; (2) removing recommendations regarding monitoring; (3) increasing the number of women recommended for reproducibility studies; (4) recommending intermediate-term precision studies in addition to short-term precision studies; (5) deleting the recommendation that separate T-score thresholds be determined for reference databases based on non-Caucasian females or males of any ethnicity; (6) recommending justification for exclusion criteria regarding recent use of bone-active drugs; (7) recommending stratification of patients by bone mineral density rather than age for reproducibility testing; (8) recommending inclusion of axial dual energy x-ray absorptiometry data in order to determine level of discordance with bone sonometer; and (9) recommending testing to assess temperature dependence of measurements.

The agency disagreed with the suggestion to require that bone sonometers express measurements in terms of fracture risk instead of T-scores. FDA recognizes the diagnostic significance of fracture risk and the limitations of T-scores. Previously-approved bone sonometers, however, express measurements in terms of T-scores because they were developed and approved prior to recent publications reporting limitations of T-scores. Because currently approved bone sonometers express measurements in terms of T-scores, firms wishing to demonstrate substantial equivalence of new bone sonometers with similar indications and technology may choose to express diagnostic measurements in terms of T-scores. The agency distinguishes this goal from that of demonstrating the safety and effectiveness of bone sonometers using new technology, or, with new indications for use, such as fracture risk measurement. As yet, a standardized measure of fracture risk has not been introduced into clinical practice, although FDA is aware that such efforts are currently underway. The agency encourages these efforts. If and when a standard method to predict fracture risk becomes available, FDA may revise the bone sonometers guidance.

#### **IV. FDA's Conclusions**

Based on the information discussed in the preamble to the proposed rule (71 FR 7894), and revisions to the guidance as discussed previously in this document, FDA concludes that special controls, in conjunction with general controls, will provide reasonable assurance of the safety and effectiveness of bone sonometers. The agency is, therefore, reclassifying bone sonometers from class III (premarket approval) into class II (special controls) when intended for determining the possible presence of osteoporosis and/or assessing non-age-related bone loss. Elsewhere in this issue of the **Federal Register**, FDA is

announcing the availability of the guidance document entitled “Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document; Bone Sonometers” as the special control capable of providing reasonable assurance of safety and effectiveness for these devices. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a bone sonometer intended for determining the possible presence of osteoporosis and/or assessing non-age-related bone loss will need to address the issues covered in the special controls 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 for bone sonometers by adding new § 892.1180. For the convenience of the reader, 21 CFR 892.1 has been amended to inform the reader where to find guidance documents referenced in 21 CFR part 892.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, this type of device is not exempt from premarket notification requirements. Persons intending to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the bone sonometer(s) intended for marketing.

## **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, 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 certifies that this final rule is not a significant regulatory action as defined by 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 bone sonometers from class III to class II relieves manufacturers of this device type 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 type, 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.

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 any

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 \$127 million, using the most current (2006) 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 Executive order and, consequently, a federalism summary impact statement is not required.

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

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

This final rule also designates a guidance document as a special control. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of that guidance document entitled “Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers,” which contains a Paperwork Reduction Act analysis for that guidance.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 892 continues to read as follows:

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

■ 2. Add § 892.1(e) to read as follows:

§ 892.1 Scope.  
\* \* \* \* \*

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

■ 3. Add § 892.1180 to subpart B to read as follows:

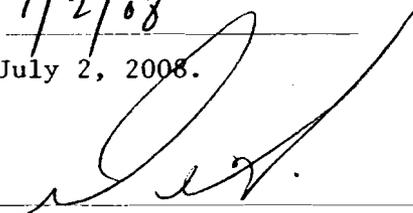
§ 892.1180 Bone sonometer.

(a) Identification. A bone sonometer is a device that transmits ultrasound energy into the human body to measure acoustic properties of bone that indicate overall bone health and fracture risk. The primary components of the device are a voltage generator, a transmitting transducer, a receiving transducer, and hardware and software for reception and processing of the received ultrasonic signal.

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S. Karakostas, FR  
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(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers." See § 892.1(e) for the availability of this guidance document.

Dated: 7/2/08  
July 2, 2008.



Daniel G. Schultz,  
Director,  
Center for Devices and Radiological Health.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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