the exemptions and were able to defer the equipage costs for several years. Since that time, technology developments and the availability of Mode S avionics dictate that we revise our policy. As we are retaining the Mode S transponder requirements, the basis for the current exemptions no longer exists. Operators are not entitled to an exemption as a matter of right. Consequently, we do not agree with RAA's assertion that the previous grant of exemptions is tantamount to a rule and thus deserving of a cost-benefit analysis. We did view, as critical and warranting public input, the appropriate date for which the exemptions would terminate and that affected operators would be required to install a Mode S transponder if their Mode C or Mode A transponder could not be repaired and specifically requested comment on that aspect.

RAA also stated that there are more than 130,000 general aviation users who are not required to install Mode S and questioned why the Mode S transponder are required for part 135 operators.

The Mode S transponder requirement for part 91 operations was rescinded in 1992 (57 FR 34614; August 5, 1992). The agency concluded that the expense of requiring the equipment for all part 91 operators could not be justified since the vast majority of general aviation operators do not operate in congested airspace. Furthermore, to impose a Mode S requirement on all such operators would be unduly burdensome with little safety benefit. At this time, we do not see evidence that this rationale is no longer valid.

As stated previously, any new exemption or request for extension will be evaluated carefully as to whether it would serve the public interest. Requesting an exemption simply because previous exemptions have been granted is not considered in the public interest.

Adoption of the March 1, 2007 Date

The FAA concludes that March 1, 2007, provides a reasonable timeframe for the exemptions to terminate. We intend to judiciously exercise our authority in reviewing any petitions for exemption or requests for extension under 14 CFR 11.81.

Operators are advised that this policy does not require the installation of Mode S transponders on March 1, 2007. Operators may continue to use Mode A and Mode C transponders beyond the expiration of their exemption and past March 1, 2007, until they can no longer be repaired and must be replaced.

Issued in Washington, DC, on February 9, 2006.

James J. Ballough,

Director, Flight Standards Service.

[FR Doc. E6–2178 Filed 2–14–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 2005N–0467]

Medical Devices; Radiology Devices; Reclassification of Bone Sonometers

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing a proposed rule to reclassify bone sonometer devices from class III into class II, subject to special controls. 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. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document entitled ''Class II Special Controls Guidance Document: Bone Sonometers'' that the agency proposes to use as a special control for these devices.

DATES: Submit comments by May 16, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0467, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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, 301–594–1212, ext. 130.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authority

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1979 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (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 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 part 807 (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) 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 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 History of the Device

A bone sonometer is a postamendments device classified into class III under section 513(f)(1) of the act. Therefore, this generic type of device cannot be placed in commercial distribution unless it is reclassified under section 513(f)(3), or is the subject of a PMA or notice of completion of a product development protocol under section 515 of the act (21 U.S.C. 360e). Accordingly, under section 513(f)(3) of the act, FDA is initiating this proposal to reclassify bone sonometers from class III to class II when intended for the following: (1) Determining the possible presence of osteoporosis and assessing fracture risk, (2) monitoring bone changes over time, and/or (3) assessing non-age-related bone loss.

III. Device Description

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. Bone sonometers are used for determining the possible presence of osteoporosis and assessing fracture risk; monitoring bone changes over time; and assessing non-age-related bone loss. The primary components of the device are a voltage generator, a transmitting transducer, a receiving transducer, hardware, and software for reception and processing of the received ultrasonic signal. By processing an ultrasonic signal propagated through a bone, it is possible to estimate broadband ultrasonic attenuation (BUA) and/or speed of sound (SOS). These two acoustic parameters have also been shown in prospective clinical trials to predict fracture incidence (Refs. 1 and 2). In this way, BUA and SOS can be used to aid a physician in determining the possible presence of osteoporosis and assessing fracture risk; monitoring bone changes over time; and assessing non-age-related bone loss.

IV. Summary of the Data Upon Which the Reclassification is Based

FDA is proposing this reclassification based on experience with the device and information on the benefits and risks of the device that have developed since the device's classification into class III. Specifically, distinct bone sonometers from different manufacturers demonstrate similar performance and increases the agency's confidence in this technology. In addition, a recent study of 149,524 women compared four peripheral techniques, including bone sonometry, peripheral dual energy x-ray absorptiometry (DEXA), finger DEXA, and heel single x-ray absorpiometry, for their ability to predict fracture incidence within one year of measurement. (Ref. 3.) The results show that all four techniques were equally effective for this purpose. Peripheral DEXA and finger DEXA are in class II.

Moreover, as discussed next, information regarding the risks of the device, along with measures to mitigate these risks, has developed. FDA believes this information is sufficient to establish special controls for this device that will provide a reasonable assurance of its safety and effectiveness if it is reclassified into class II.

V. Risks to Health

FDA believes that bone sonometers, when used for determining the possible presence of osteoporosis and assessing fracture risk; monitoring bone changes over time; or assessing non-age-related bone loss; should be reclassified into class II because special controls, in addition to general controls, can provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance. After considering the information regarding bone sonometer use and technology, published literature, and medical device reports, FDA has evaluated the risks to health associated with use of these devices. FDA believes that electrical shock; electromagnetic compatibility; tissue damage; and inaccurate measurement present risks to health associated with the use of bone sonometers. The draft special controls guidance document entitled ''Class II Special Controls Guidance Document: Bone Sonometers'' aids in mitigating the risks by recommending performance characteristics, safety testing, and appropriate labeling.

VI. Special Controls

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft guidance document entitled ''Class II Special Controls Guidance Document: Bone Sonometers,'' that the agency is proposing to use as the special control for these device types. The draft guidance document contains specific recommendations with regard to device performance testing and other information that should be included in a premarket (510(k)) notification submission. Particular sections of the guidance document address the following: (1) Electrical safety, (2) electromagnetic compatibility, (3) acoustic intensity, (4) device performance characteristics, and (5) labeling. FDA believes that this draft special controls guidance, in addition to general controls, can address the risks to heath described in section V of this document.

In table 1 of this document, FDA has identified the risks to health associated

with the use of these devices in the first column and the recommended mitigation measures identified in the draft class II special controls guidance document in the second column. These recommendations will also help ensure that the device has appropriate performance characteristics and labeling for its use.

Following the effective date of any final reclassification rule based on this proposal, any firm submitting a 510(k) submission for a bone sonometer device will need to address the issues covered in the class II special controls guidance document. However, the firm need only show that its device meets the recommendations of the class II special controls guidance document or in some other way provides equivalent assurances of safety and effectiveness.

TABLE 1

Identified Risk	Recommended Mitigation Measures
Electrical shock	Electrical Safety
Electromagnetic interference	Electromagnetic Compatibility
Tissue damage	Acoustic Intensity
Inaccurate measurement leading to inappropriate therapy	Non-Clinical Testing Clinical Testing Labeling

VII. FDA's Findings

FDA believes that bone sonometers should be reclassified into class II because special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of these devices, and there is sufficient information to establish special controls to provide such assurance. FDA, therefore, is proposing to reclassify bone sonometers into class II and establish the class II special controls guidance document as a special control for these devices.

FDA believes for this type of device, premarket notification is necessary to provide reasonable assurance of the device's safety and effectiveness; therefore, the device would not be exempt from premarket notification requirements (section 510 of the act). Thus, 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 device they intend to market.

VIII. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

IX. 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.

X. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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 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 these devices from class III to class II will relieve all 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. The agency, therefore, certifies that this proposed rule, if finalized, 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 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 $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

XI. Federalism

FDA has analyzed this proposed 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.

XII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the special controls guidance document identified by this proposed rule does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal**

Register, FDA is publishing a notice announcing the availability of the draft guidance document entitled ''Class II Special Controls Guidance Document: Bone Sonometers.'' The notice contains an analysis of the paperwork burden for the draft guidance.

XIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

XIV. References

The following references have 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. Bauer, D. C., et al., ''Broadband Ultrasound Attenuation Predicts Fractures Strongly and Independently of Densitometry in Older Women,'' *Archives of Internal Medicine*, 157, pp. 629–634, 1997.

2. Hans, D., et al., ''Ultrasonographic Heel Measurements to Predict Hip Fracture in Elderly Women: The EPIDOS Prospective Study,'' *Lancet*, 348, pp. 511–514, 1996.

3. Miller, P. D., et al., ''Prediction of Fracture Risk in Postmenopausal White Women With Peripheral Bone Densitometry: Evidence From the National Osteoporosis Risk Assessment,'' *Journal of Bone and Mineral Research*, 17, pp. 2222–2230, 2002.

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 the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 892 be 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 section 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.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Bone Sonometers.'' See § 892.1(e) of this chapter for the availability of this guidance document.

Dated: January 17, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–2076 Filed 2–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 67 and 68

[USCG–2005–20258]

RIN 1625–AA95

Vessel Documentation: Lease Financing for Vessels Engaged in the Coastwise Trade

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend its regulations for documenting lease-financed vessels that have a ''coastwise endorsement'' (i.e., vessels used in trade and passenger service within the U.S. or between U.S. ports and those used in dredging and towing in U.S. waters). The vessels affected by this proposal are owned by foreign-owned or controlled U.S. companies, where there is a ''demise charter'' to a U.S. citizen (i.e., an agreement for the charterer to assume responsibility for operating, crewing, and maintaining the vessel as if the charterer owned it).

DATES: Comments and related material must reach the Docket Management Facility on or before May 16, 2006. Comments sent to the Office of Management and Budget (OMB) on collection of information must reach OMB on or before May 16, 2006.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2005–20258 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Web Site: *http://dms.dot.gov.*

(2) Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Washington, DC 20590–0001.

(3) Fax: 202–493–2251.

(4) Hand delivery: Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(5) Federal eRulemaking Portal: *http://www.regulations.gov.*

You must also mail comments on collection of information to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Patricia Williams, Deputy Director, National Vessel Documentation Center, Coast Guard, telephone 304–271–2506. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–493–0402.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://dms.dot.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.