

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

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[Docket No. FDA-2008-N-0273]

Medical Devices; Radiology Devices; Reclassification of Full Field Digital Mammography System

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the full field digital mammography (FFDM) system from class III (premarket approval) to class II (special controls). The device type is intended to produce full field digital x-ray images of the breast. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance document entitled "Class II Special Controls Guidance Document: Full Field Digital Mammography System" that would serve as the special control for the device, if FDA reclassifies this device type.

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the Federal Register*]. See section X of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2008-N-0273, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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 previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

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.regulations.gov>, including any personal information provided. For additional information on submitting comments, 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.regulations.gov> 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, 240-276-3666.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by (among other amendments) the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (Public Law 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, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments) as “preamendments” devices. FDA classifies these devices after the agency takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Under section 513 of the act, FDA refers to devices that were not in commercial distribution prior to May 28, 1976, as “postamendments” devices.

Postamendments devices are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless 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) of the regulations.

Reclassification of classified postamendments devices is governed by section 513(f)(3) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device into 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 these class III devices. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(3)(B)(i) of the act, the Secretary may ask for a recommendation from a device classification panel on a proposed reclassification, whether initiated by FDA or a petitioner. The panel will make a recommendation to FDA concerning the proposed reclassification. The recommendation must contain the following information: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which

the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device that is the subject of the proposed reclassification.

II. Regulatory History of the Device

An FFDM system is a postamendments device classified into class III under section 513(f)(1) of the act. This generic type of device cannot be placed in commercial distribution unless it is reclassified under section 513(f)(3) or subject to an approval of a premarket approval (PMA) application under section 515 of the act (21 U.S.C. 360e). In accordance with section 513(f)(3) of the act and based on information regarding the device, FDA, on its own initiative, is proposing to reclassify this device type from class III to class II when intended to produce full field digital x-ray images of the breast. Consistent with the act and the regulation, FDA referred the proposed reclassification to the Radiological Devices Panel (the Panel) for its recommendation on the requested change in classification.

III. Device Description

An FFDM system is a device intended to be used to produce full field digital x-ray images of the breast. This generic type of device may include one or more of the following: Digital mammography software, full field digital image receptor, acquisition workstation, and signal analysis programs. Mammographic x-ray producing equipment (x-ray generator, x-ray control, x-ray tube, collimator, beam filter, and breast compression system) and display accessories are regulated under 21 CFR 892.1710, 892.2040, and 892.2050 as class II devices (special controls).

IV. Recommendations of the Panel

At a public meeting on May 23, 2006, the Panel unanimously recommended that the FFDM system be reclassified from class III to class II

(special controls). The Panel believed that class II with the draft special controls guidance document, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device (Ref. 1).

V. Risks to Health

After considering the information in the Panel's recommendation, published medical literature (Refs. 2 through 4), and device recalls (Ref. 5), FDA determined that the potential risks to health associated with use of the FFDM system are electrical hazards, corrupted or non-diagnostic image, incorrect patient positioning, excessive x-ray exposure, excessive breast compression, and infection and skin irritation. FDA's draft special controls guidance document aids in mitigating the potential risks by recommending electrical safety characteristics, physical laboratory testing, clinical studies, and labeling. (See table 1 in section VIII of this document.)

VI. Summary of Reasons for Recommendation

After reviewing the data provided by FDA, and after considering the open discussions during the Panel meeting and the Panel members' personal knowledge of and clinical experience with the device, the Panel recommended that FDA reclassify the FFDM system intended to produce full field digital x-ray images of the breast from class III into class II (special controls). The Panel believes that the special controls discussed in section VIII of this document, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide this assurance (Ref. 1).

VII. Summary of Data Upon Which the Panel Recommendation Is Based

After considering the Panel's recommendation, as well as the medical literature and other information, FDA believes that the potential risks to health associated with the FFDM system are addressed in the draft special controls

guidance document. FDA also believes that the draft guidance would provide reasonable assurance of the safety and effectiveness of the FFDM system regarding the identified risks to health of this device.

VIII. Special Controls

In addition to general controls, FDA believes that the draft special controls guidance document is an adequate special control to address the risks to health associated with the use of the device described in section V of this document. FDA believes that special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance entitled “Class II Special Controls Guidance Document: Full Field Digital Mammography System” that the agency intends to use as the special control for this device. The draft guidance addresses the information FDA believes should be included in a premarket notification submission (510(k)) for the FFDM system. FDA has identified the risks to health associated with the use of the device in the first column of table 1 of this document. The recommended mitigation measures identified in the class II special controls guidance document is in the second column of table 1 of this document.

TABLE 1.—RISKS TO HEALTH AND MITIGATION MEASURES

Identified Risk	Recommended Mitigation Measures
Electrical hazards	Electrical safety
Corrupted or non-diagnostic image	Physical laboratory testing Clinical studies
Incorrect patient positioning	Clinical studies
Excessive x-ray exposure	Physical laboratory testing
Excessive breast compression	Physical laboratory testing
Infection, skin irritation	Labeling

Following the effective date of a final rule based on this proposal, any firm submitting a 510(k) for an FFDM system 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.

IX. FDA's Tentative Findings

FDA and the Panel believe that the FFDM system should be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide this assurance. FDA, therefore, is proposing to reclassify the device type from class III into class II with the draft guidance as the special control for the device.

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 provide reasonable assurance of the safety and effectiveness of the device. For this device, however, FDA believes that premarket notification is necessary to provide reasonable assurance of safety and effectiveness and, therefore, does not intend to exempt the device from the premarket notification requirements.

X. Proposed 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**.

XI. 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.

XII. Analysis of Impacts

FDA has examined the impacts of the proposed 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 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. Because reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act and may permit small potential competitors to enter the market place by lowering their costs, the agency certifies that the proposed 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 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

proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

XIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed 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 tentatively concluded that the proposed 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.

XIV. 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 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 announcing the availability of the draft guidance document entitled “Class II Special Controls Guidance Document: Full Field Digital Mammography System;” the document addresses the paperwork burden for the draft guidance.

XV. 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments and submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

XVI. 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. Radiological Devices Panel, Transcript, pp. 142–156, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=659>, May 23, 2006.
2. Pisano, E., Gatsonis, C., Hendrick, E., et al., “Digital Mammographic Imaging Screening Trial (DMIST) Investigators Group,” “Diagnostic Performance of Digital Versus Film Mammography for Breast-Cancer Screening,” *New England Journal of Medicine*, 353: 1773–1783, 2005.
3. Yaffe, M., Bloomquist, A., Mawdsley, G., et al., “Quality Control for Digital Mammography: Part II Recommendations From the ACRIN DMIST Trial,” *Medical Physics*, 33(3): 737–752, 2006.
4. Thomas, J., Chakrabarti, K., Kaczmarek, R., et al., “Contrast Detail Phantom Scoring Methodology,” *Medical Physics*, 32(3), 807, 2005.

5. Device recalls are described in FDA's briefing information, slide number 12, available at http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4219b1_04_draft%20FDA%20presentation.pdf.

List of Subjects in 21 CFR Part 892

Medical device, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under 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. Section 892.1 is amended by adding paragraph (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. Section 892.1715 is added to subpart B to read as follows:

§ 892.1715 Full field digital mammography system.

(a) *Identification.* A full field digital mammography system is a device intended to produce full field digital x-ray images of the breast. This generic type of device may include one or more of the following: Digital mammography software, full field digital image receptor, acquisition workstation, and signal analysis programs.

(b) *Classification.* Class II (special controls). The special control for the device is FDA's guidance document entitled "Class II Special Controls

Guidance Document: Full Field Digital Mammography System.” See 892.1(e)
for the availability of this guidance document.

Dated: 5/21/08
May 21, 2008.



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

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