

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0275]

**Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Full Field Digital Mammography System; Availability**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Full Field Digital Mammography System." This draft guidance document describes a means by which the full field digital mammography (FFDM) system may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify the FFDM system device type from class III (premarket approval) into class II (special controls). This draft guidance is neither final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Class II Special Controls Guidance Document: Full Field

PDm

Display Date 5-29-08

Publication Date 5-30-08

Comments Release

Digital Mammography System” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

**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**

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, 21 CFR 892.2040, and 21 CFR 892.2050 as class II devices (special controls). The FFDM system device

is currently in class III and subject to premarket approval requirements (section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e)).

At a public meeting on May 23, 2006, the Radiological Devices Panel (the Panel) unanimously recommended that the FFDM system be reclassified from class III to class II (special controls). The Panel also recommended that class II with a special controls guidance document would provide reasonable assurance of the safety and effectiveness of the device. FDA considered the Panel's recommendations, and elsewhere in this issue of the **Federal Register**, FDA is proposing to reclassify the FFDM system into class II. If the reclassification rule is finalized, FDA intends that this draft guidance document will serve as the special control for this device.

Following the effective date of any final reclassification rule based on the proposal, any firm submitting a premarket notification (510(k)) for an FFDM system would need to address the issues covered in the special controls draft guidance document. However, the firm need only show that its device meets the recommendations of the draft guidance document or in some other way provides equivalent assurances of safety and effectiveness.

## **II. Significance of Guidance**

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent the agency's current thinking on the FFDM system. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## **III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Class II Special Controls Guidance

Document: Full Field Digital Mammography System,” you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1616) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturer’s assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.regulations.gov>.

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

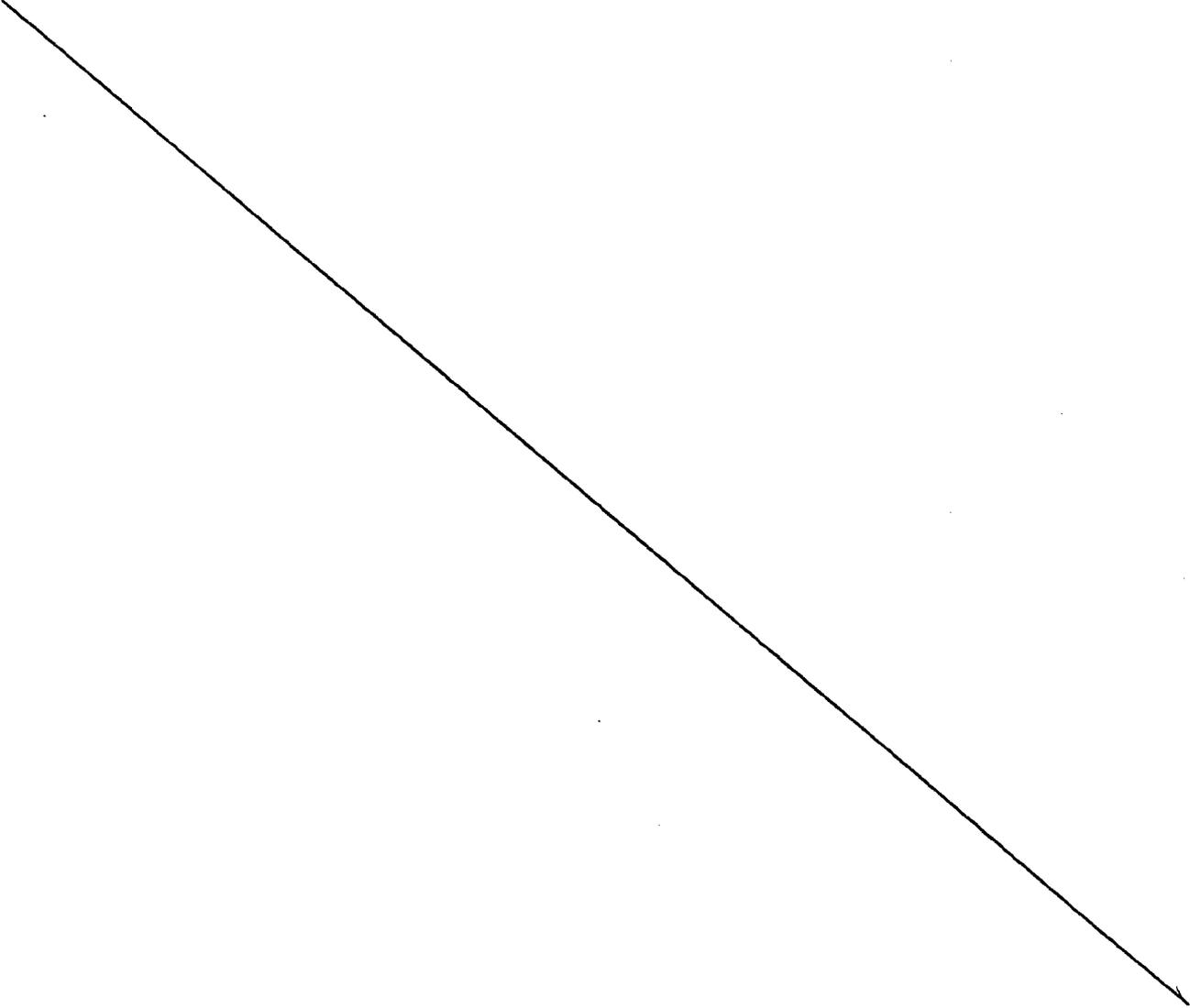
This draft guidance document refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

#### **V. Comments**

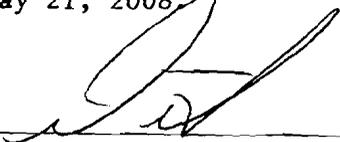
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed

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 Division of Dockets Management 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>*.



Dated: 5/21/08  
May 21, 2008



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

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