Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to **CDRH-Guidance@fda.hhs.gov (mailto:CDRH-Guidance@fda.hhs.gov)** to receive a copy of the guidance. Please use the document number 1617 to identify the guidance you are requesting.

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Guidance for Industry and FDA Staff

Display Accessories for Full-Field Digital Mammography Systems - Premarket Notification (510(k)) Submissions

1. Introduction

FDA has developed this guidance document to assist industry in preparing premarket notification submissions for display accessories of full-field digital mammography (FFDM) systems. These devices are classified as Class II and subject to special controls (see 21 CFR 892.2040 and 21 CFR 892.2050). The devices are intended to provide display of digital mammographic images for review in the screening and diagnosis of breast cancer.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "**A Suggested Approach to Resolving Least Burdensome Issues (/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm)**" document.

The firm must show that its device addresses the issues of safety and effectiveness identified in this guidance, either by meeting the recommendations of this guidance or by some other means that provides equivalent assurances of safety and effectiveness.

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2. Background

A manufacturer who intends to market a device of this generic type must conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E; the applicable special controls (see 21 CFR 892.2040 and 21 CFR 892.2050); and obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.81 and 807.87.) This guidance document identifies the classification regulations and product codes for display accessories to FFDM systems (refer to **Section 4. Scope**). Other sections of this guidance document provide information to manufacturers on addressing risks related to these devices in premarket notifications (510(k)s.

This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, the guidance, **Format for Traditional and Abbreviated 510(k)s**,[1] and the section of CDRH's Device Advice, **Premarket Notification 510(k)**.[2]

As described in the guidance entitled, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**,[3] a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA issues a Class II special controls guidance document. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

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3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), we recommend that you include an Abbreviated 510(k) summary report of appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g). Therefore, we recommend that you include an Abbreviated 510(k) summary report. The Abbreviated 510(k) summary report should describe how you may have incorporated the recommendations of this guidance document during the device development and testing. The Abbreviated 510(k) summary report should also briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

Proposed labeling

Proposed labeling must be sufficient to describe the device, its intended use, and the directions for its use (21 CFR 807.87(e)). (Please refer to **Section 8. Labeling** for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Abbreviated 510(k) Summary report[4]

FDA recommends that the summary report contain the following:

Description of the device and its intended use

We recommend that you describe the performance specifications and, when appropriate, include detailed, labeled drawings of the device. (Please refer to **Section 5.Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an “indications for use” enclosure.[5]

Description of device design

Please include a brief description of the device design requirements (21 CFR 807.87(f)).

Identification of the risk analysis method

We recommend that you identify the risk analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design and the results of this analysis. (Please refer to **Section 6.Risks to Health** for the risks to health FDA has identified as generally associated with the use of this device.)

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the risks identified in this guidance document, as well as any additional risks identified in your risk analysis.

Description of the performance aspects

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Section 7. Physical Laboratory Testing** of this guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[6] (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

Reliance on standards

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either of the following:

- a statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- a declaration of conformity to the standard.[7]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the Act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations**.[8]

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting Special 510(k)s.

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4. Scope

The scope of this document is limited to display accessories described in 21 CFR 892.2040 (product code, LMC) and 21 CFR 892.2050 (product code, LLZ) for FFDM systems. Display accessories for FFDM systems are Class II devices used for the display of medical images of the breast.

21 CFR 892.2040 Medical image hardcopy device

(a) Identification. A medical image hardcopy device is a device that produces a visible printed record of a medical image and associated identification information. Examples include multiformat cameras and laser printers.

(b) Classification. Class II (special controls; voluntary standards--Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

21 CFR 892.2050 Picture archiving and communications system

(a) Identification. A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

(b) Classification. Class II (special controls; voluntary standards--Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

Medical image hardcopy devices must comply with the requirements of 21 CFR 892.2040(b). Picture archiving and communications systemsmust comply with the requirements of 21 CFR 892.2050(b).

This guidance does not address ophthalmic hardcopy image devices (product code, NFI) classified under 21 CFR 892.2040 or ophthalmic image management systems (product code, NFJ) classified under 21 CFR 892.2050.

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5. Device Description

You should identify your device by the regulation and product code as described in **Section 4. Scope**.

FFDM system accessories are output display devices such as workstations, printers, and monitors for the display and simple manipulation of images for primary mammographic image diagnosis. Multi-modality picture archiving and communication systems (PACS) or general use printers that have performance characteristics and specifications that make them usable for primary image interpretations in an FFDM system can also be used as FFDM accessories. Because processing, presentation, and display of digital mammograms are important in producing images suitable for primary diagnosis, the 510(k) submission for a FFDM system accessory should contain a description of all processing stages from the input FFDM data to the displayed, printed, and archived outputs.

We recommend that you provide a complete description of the FFDM system display accessory as discussed below.

Soft-Copy Display System

Soft-copy display systems include a display device or monitor and a display controller. We recommend you provide the following:

- a complete description of the entire display system, including the display device, display controller or graphics card, and software for the control of display functions, calibration, and image manipulation;
- the speed and bit-depth precision of digital-to-analog converters;
- the physical size of the display available for image visualization; and
- the pixel array dimensions, pixel size, and pixel pitch.

Hard-Copy Display System

Hard-copy display systems produce a printout of the digital image on a radiographic film. We recommend you describe the following:

- pixel size;

- spatial resolution;
- maximum size of the recording pixel matrix;
- gray scale resolution;
- minimum and maximum optical densities
- look-up table;
- maximum and minimum optical density; and
- film loading.

Picture Archiving and Communications System (PACS)

A Picture Archiving and Communications System (PACS) is a digital archiving system. These systems generally have data security features, e.g., access by authorized personnel only, retention of case, image, and patient information. We recommend you describe the following:

- system and components with associated diagrams (refer to **Guidance for the Submission of Premarket Notifications for Medical Image Management Devices**[9]);
- data handling, storage, and security features; and
- data compression[10] algorithms, if used.

Review Workstation

A review workstation includes display hardware (monitor) and installed software used for image review and manipulation.

We recommend you provide the following:

- computer operating system specifications;
- a description of all image manipulation tools that are available to the user;
- a snapshot of the graphical-user interface (GUI); and
- an explanation of the functions on each button or key on the GUI.

Image Review Manipulation Software

The software for image review and manipulation is installed on a review workstation to allow image manipulation (i.e., zoom, contrast enhancement, window and level functions, and quantification tools).

We recommend you provide the following:

- a description of the software functions;

- a detailed flow-chart of the algorithms; and
- the name and characteristics of the review workstation compatible with the software.

For review workstation and image review manipulation software, we also recommend that you submit the information for software-controlled devices described in **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**[11] and in**Guidance for Off-the-Shelf Software Use in Medical Devices**.[12] The kind of information we recommend you submit is determined by the "level of concern," which is related to the risks associated with software failure. The level of concern for a device may be minor, moderate, or major. The level of concern for these devices is usually moderate.

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6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of FFDM system accessories addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. We recommend that you conduct a risk analysis to identify any other risks specific to your device and include the results of this analysis. The 510(k) should also describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Identified Risk	Recommended Mitigation Measures
Inaccurate data display	7. Physical Laboratory Testing 8. Labeling

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7. Physical Laboratory Testing

We recommend you provide the following technical information with a comparison to the legally marketed predicate device.

Soft-Copy Display System

We recommend you provide a description of all proprietary measuring systems used for performing quantitative tests, including trade name, characteristics, and accuracy of the measurement tools. You should perform the following tests:

- luminance response;
- luminance uniformity;
- geometrical distortion;
- display reflections, including specular, diffuse, and haze components;
- small-spot contrast ratio;
- spatial resolution (expressed as modulation transfer function (MTF) along horizontal and vertical directions);
- noise (expressed as noise power spectrum (NPS) along horizontal and vertical directions);
- pixel aperture ratio;
- phosphor type;[13]
- chromaticity (color coordinates or full spectrum) measured at the center of the screen at 5%, 50%, and 95% of the maximum luminance;
- chromaticity uniformity using at least a 5-point sample (center and corners);
- pixel defects/faults (including spatial distribution and type of defect specifications);
- description of presence or absence of artifacts: phase or clock issues, miscellaneous issues, including ringing, ghosting, and image sticking;
- temporal response, e.g., rise and fall time for 5-95%, 20-30%, 40-60% transitions; and
- performance data on stability of luminance (effect of temperature and time on the luminance).

Your luminance response testing should address:

- maximum and minimum achievable luminance;
- maximum and minimum recommended (operational) luminance;
- effective luminance bit-depth by performing visual evaluation of a gradient test pattern;
- intrinsic (uncorrected) luminance response at each command level;
- calibration to a grayscale function (i.e., Digital Imaging and Communications in Medicine (DICOM) Grayscale Standard Display Function) at each digital value;
- angular dependency of luminance at 30 and 45 degrees in horizontal, vertical, and diagonal directions.[14]

For methods and procedures for display characterization, please refer to the following:

- TG18[15] (American Association of Physicists in Medicine, Task Group 18, Assessment of Display Performance for Medical Imaging Systems); and
- VESA Flat Panel Display Metrology (FPDM) Standard version 2.0; Flat Panel Display

Measurements Standard Working Group, Video Electronics Standards Association; Flat Panel Display Measurements Standard, version 2.0., Technical Report, VESA, 2001.

Hard-Copy Display System (printer)

We recommend you provide technical characteristics, including quantitative measures of the following:

- sensitometric response (e.g., gamma, brightness versus digital value);
- spatial resolution such as the modulation transfer function (MTF);
- artifacts and electronic noise such as the noise power spectrum (NPS); and
- dynamic range.

In accordance with 21 CFR 807.87(l), we may, if necessary, request that you provide a representative set of printout images.

Picture Archiving and Communications System (PACS)

PACS devices are generally combinations of workstations, software, communications components, monitors, and/or associated hardware. We recommend you perform the same testing and provide the same information as you would for the individual components.

Image Review Manipulation Software

We recommend you provide the following:

- a description of the validation or testing paradigm used;
- the number of validation or testing cases, and its relevance;
- the definition of the performance metric;
- reader's qualification for validation, and the number of readers, if readers are involved;
- the performance accuracy indices with associated confidence intervals or error bars; and
- the description of how the user will be able to identify suitability of the output of each function of the software, and any control failures.

Review Workstation

Workstations are generally combinations of a softcopy display device, image manipulation software, a computer platform, and associated hardware. We recommend you perform the same testing and provide the same information as you would for the individual components.

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8. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are intended to assist you in preparing labeling that satisfies the requirements of 21 CFR Part 801.[16]

Directions for Use

We recommend submitting clear and concise instructions for use that delineate the technological features of the specific device and how the device is to be used. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner. As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use.

Your labeling should include the following:

- indications for use;
- warnings and precautions;
- description of the device and any associated devices with illustrations;
- cleaning information;
- conformity to any voluntary standards;
- manufacturer's contact information;
- performance specifications (summary of physical laboratory testing); and
- a full description of the quality assurance tests (and action limits), including detailed procedures for performing these tests, if applicable, and the frequency of testing. You may use the latest recognized version of *NEMA Standards XR 22 and XR 23,* for designing quality assurance tests.

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[1] See, **Format for Traditional and Abbreviated 510(k)s (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm)**.

[2] See, **Device Advice: Premarket Notification 510(k) (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm)**.

[3] See, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm)**

[4]An abbreviated 510(k) summary report is intended to explain how a device-specific guidance document was used during development and testing of your device. This is not the 510(k) summary described in 21 CFR 807.92, which may be submitted to satisfy 21 CFR 807.87(h). For additional information on abbreviated 510(k) summary reports, see section 9 of **Format for Traditional and Abbreviated 510(k)s (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm)**.

[5] Refer to the for the **recommended format (http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm360431.pdf)** (PDF File Size: 1.03MB).

[6] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[7] See, **Required Elements for a Declaration of Conformity to a Recognized Standard (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm)**(Screening Checklist for All Premarket Notification [510(k)] Submissions).

[8] See, **Guidance for Industry and for FDA Staff Use of Standards in Substantial Equivalence Determinations (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm)**.

[9] See, **Guidance for the Submission Of Premarket Notifications for Medical Image Management Devices (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073720.htm)**.

[10] See, **MQSA Policy Guidance Help System (/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm)**.

[11] See, **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm)**.

[12] See, **Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices (ssLINK/ucm073778.htm)**.

[13] Tests apply only to cathode-ray tube displays.

[14] Tests apply only to liquid crystal displays.

[15] **http://deckard.mc.duke.edu/~samei/tg18 (http://deckard.mc.duke.edu/~samei/tg18)**.

[16]Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce.

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)