Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Breast Lesion Documentation System

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Obestetrics/Gynecology Branch
Division of Reproductive, Abdominal & Radiological Devices
Office of Device Evaluation

Preface

Public Comment:

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, 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 **1202** to identify the guidance you are requesting.

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Guidance for Industry and FDA Staff
Class II Special Controls Guidance Document: Breast Lesion Documentation System

1. Introduction

This guidance document was developed as a special control guidance to support the classification of the breast lesion documentation system into class II. The device, as classified, is intended to produce a surface map of the breast as an aid in document palpable breast lesions identified during a clinical breast exam.

This guidance is issued in conjunction with a Federal Register notice announcing the classification of the breast lesion documentation system.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a breast lesion documentation 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.

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

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of breast lesion documentation systems. Thus, a manufacturer who intends to market a device of this generic type should (1) conform to the general controls of the Act including the 510(k) requirements described in **21 CFR 807 Subpart E (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807&showFR=1)**, (2) address the specific risks to health associated with breast lesion documentation systems identified in this guidance and, (3) obtain a substantial equivalence determination from FDA prior to marketing the device. (See also **21 CFR 807.85 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=807.85)**.)

This special control guidance document identifies the classification regulations and product codes for the breast lesion documentation system to which it applies (refer to **Section 4 – Scope**). In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with general controls, will generally address the risks associated with breast lesion documentation systems and lead to a timely 510(k) review and clearance. This document supplements other agency documents regarding the specific content requirements of a 510(k) submission. You should also refer to **21 CFR 807.87 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=807.87)** and other agency documents on this topic, such as **Premarket Notification: 510(k)**.[1]

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance** ,"[2] 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 a Class II Special Controls Guidance Document has been issued. Manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

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 comply with the statutory and regulatory criteria in the manner suggested by the guidance and in your attempt to 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** "[3] document.

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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 proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should 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 guidance document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 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 Class II Special Controls Guidance Document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to **Section 8** for specific information that we recommend you include in the labeling for devices of the types covered by this guidance document.)

Summary report

We recommend that the summary report contain:

- Description of the device and its intended use. The description should include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Refer to **Section 5** for specific information that should be included in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.
- Description of device design requirements.
- Identification of the Risk Analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to **Section 6** for the risks to health generally associated with the use of this device that FDA has identified.)
- Discussion of the device characteristics that address the risks identified in this Class II Special

Controls Guidance Document, as well as any additional risks identified in your risk analysis.

- A brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 6** and **7** of this Class II Special Controls 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 should 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.[5] (See also **21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=820.30)**.)

If any part of the device design or testing relies on a recognized standard, (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard.[6] **Please note that testing must be completed before submitting a declaration of conformity to a recognized standard**. (21 USC 514(c)(2)(B)). For more information, see FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA** .[7]

If it is not clear how you have addressed the risks identified by FDA or 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 modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification for a breast lesion documentation system.

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4. Scope

The scope of this document is limited to the following device an obstetrics and gynecology device under 21 CFR §884.2990, product code NKA. This generic type of device, a breast lesion documentation system, is a device that is intended for use in producing a surface pressure map of

the breast as an aid to document palpable breast lesions identified during a clinical breast exam.

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5. Device Description

We recommend that you identify your device by regulation and product code and include the information below. We also recommend that you provide summary information in tabular form comparing your device with the predicate. We recommend that you include the information described below in a table, without any photographs or drawings.

Device components and theory of operation

We recommend that you identify all components, system software, and accessories within the scope of the 510(k), and any collateral devices that can be connected or used with the monitor (e.g., personal computers (PCs), printers).

Photograph or drawing of the device

We recommend that you also provide a photograph or drawing of the device. You should also provide a functional block diagram (including all accessories).

Functional performance characteristics

We recommend that you describe the functional performance characteristics of the device.

Software

We recommend that you describe any software included.

Patient contacting materials

We recommend that you identify all the materials in the patient contacting components of the device.

Comparison to the predicate device

We recommend that you:

- identify a legally marketed predicate device
- explain how your device and the predicate are similar.

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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 the breast lesion documentation system 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 also conduct a risk analysis prior to submitting your 510(k), to identify any other risks specific to your device. The premarket notification should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or have identified risks additional to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

Identified Risk	**Recommended Mitigation Measures**
Failure to produce an appropriate map	**section 7**, **10**, **11**
Misinterpretation of displayed images	**section 11**
Improper use	**section 11**
Skin irritation or toxicity	**section 8**
Electrical shock	**section 9**
Electromagnetic interference	**section 9**
Tissue trauma from mechanical injury	**section 9**

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7. Software Information

Please refer to the **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm)** (hereafter, the Software Guidance), for a discussion of the software documentation that you should provide. As discussed in the *Software Guidance*, the "level of concern" is related to the possible consequences of software failure, and may be minor, moderate, or major. The software for breast lesion documentation systems is generally considered a "minor level of concern." Because designs may differ, you should provide a clear scientific justification that discusses the possible consequences of a software failure.

If the device includes off-the-shelf software, you should provide the additional information as recommended in the **Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices (ssLINK/ucm073778.htm)**.

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8. Information on Material Safety

The device contains patient contacting parts. We recommend that you evaluate the biocompatibility of the materials in these parts as described in the **International Standard Organization (ISO) standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing**. We also recommend that you document the results in your design history file as a part of the Quality Systems Requirements (**21 CFR 820.30 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=820.30)**). We recommend that you select tests appropriate for limited contact with intact skin. If identical materials are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of performing biocompatibility testing.

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9. Bench Testing

Performance (Phantom) Testing

We recommend that you include the following (non-clinical) performance testing:
Performance testing should include a description of the test protocol(s) and describe the characteristics of the phantom (model used for the testing). In addition, we recommend that testing include an evaluation of:

- inter-observer accuracy and reproducibility to measure object size, shape, and other measured characteristics (e.g., stiffness)
- intra-observer accuracy and reproducibility to measure object size, shape, and location.
- inter-system accuracy and reproducibility to measure object size, shape, and location.

Electrical and Mechanical Safety

We recommend that you evaluate the electrical and mechanical safety of your device as well as its ability to function after exposure to environmental handling hazards. We recommend that you evaluate your device according to ***one or more*** of the following standards:

- International Electrotechnical Commission (IEC) 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety
- Underwriters Laboratory (UL) 2601-1 Amendment 1 Medical Electrical Equipment: General Requirements for Safety
- American National Standards Institute (ANSI)/AAMI ES-1 Safe current limits for electromedical

apparatus

The features and design of your device will determine which of the above standards you should use and whether other standards are appropriate in addition to or in place of these. The Obstetrics/Gynecology Branch is available to answer any question you may have about which standards are appropriate for your device's features and design.

Electromagnetic Compatibility

Electromagnetic compatibility (EMC) encompasses both emissions, which is interference with other electronic devices, and immunity, which is interference with device performance created by emissions from other electronic devices. We recommend that you evaluate the EMC of your device as discussed below.

Emissions

We recommend that EMC testing demonstrate that the device will not adversely interfere with the performance of other electronic devices (*emissions*). We recommend that testing include radio frequency (RF) electromagnetic, low frequency magnetic, and conducted emissions.

Immunity

We recommend that EMC testing also demonstrate that the device will perform as expected in the presence of other electrical and electronic devices or other sources of electromagnetic disturbance (EMD) in the intended environment of use (*immunity*). The device should operate in an acceptable manner (few EMC standards require operation within specification) during and after exposure to various forms of electromagnetic disturbance. We recommend that testing include:

- electrostatic discharge (ESD)
- radiated RF electromagnetic fields
- electrical fast transients and bursts
- surges
- conducted RF electromagnetic energy
- voltage dips, short interruptions, and voltage variations on power supply input lines
- low-frequency magnetic fields
- quasi-static electric fields.

We recommend that you test your device according to IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001) to demonstrate the EMC characteristics of your device.

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10. Performance Characteristics

Clinical Information

In accordance with the Least Burdensome provisions of the FDA Modernization Act of 1997, the agency will rely upon well-designed bench and/or animal testing rather than requiring clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While clinical studies may not be needed for breast lesion documentation systems, FDA may recommend that you collect clinical data for breast lesion documentation systems with:

- designs dissimilar from designs previously cleared under a premarket notification;
- new technology, i.e., technology different from that used in legally marketed breast lesion documentation systems
- indications for use dissimilar from legally marketed breast lesion documentation systems.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. The Obstetrics/Gynecology Branch is available to discuss any questions you may have.

If clinical data are necessary, we recommend that it address the breast lesion documentation system's performance across women with different breast sizes, ages, lesion sizes, and lesion depth. We recommend that the study design address the following:

- an evaluation of the reproducibility of intra-observer and inter-observer measurements
- a comparison of measurements of the clinical breast exam to those made with the breast lesion documentation system.

We recommend that you report the following clinical study results:

- accuracy of measurements made with the breast lesion documentation system compared to the size of lesions determined by a pathologist
- percentage of clinically detected lesions documented with the breast lesion documentation system.

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11. Recommendations for Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e). [8]

Directions for use/Physician Labeling

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we expect to see clear and concise instructions that delineate the technological features of the specific device and how the device is to be used on patients. We recommend that you include a summary of clinical study results, where applicable, addressing any limitations of the technology identified in the bench or clinicals with respect to its intended use as a method for mapping breast lesions identified during clinical palpation.

We recommend that the instructions describe the procedure for sizing and comparing structures to the clinical breast examination. We also recommend that you include the intended use and address the precautions as shown in the examples below.

Intended Use

The device is intended to produce a surface map of the breast as an aid in documenting size, shape, and location of breast lesions identified during a clinical breast exam. It is a documentation tool. It is not intended for diagnosis. The device should only be used to document a lesion already palpated on clinical breast exam. Clinical management decisions should only be made on the basis of the clinical and diagnostic examinations (e.g. ultrasound or mammography). If there is a disagreement between the examination and the record produced by the device, decisions should be made on the basis of the clinical examination.

Precautions

The device has not been shown to be effective in patients who have undergone breast augmentation, reconstructive surgery, radiation therapy, or chemotherapy for prior breast cancer.

The device should not be used on patients with open wounds of the breast, as this may increase the risk of tissue trauma, bleeding, and infection.

This device has not been shown to be useful as a diagnostic or management tool, i.e., the device should not be used to track changes in the size of a lesion.

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[1]**Premarket Notification 510(k) (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm)**

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

[3]**A Suggested Approach to Resolving Least Burdensome Issues (/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm)**

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

[5]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).

[6]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).

[7]**Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm)**

[8]Although final labeling is not required for 510(k) clearance, final labeling must also comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

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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)