4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA-2026-N-7630]

Radiology Devices; Reclassification of Digital Breast Tomosynthesis System

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed amendment; proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify digital breast tomosynthesis (DBT) systems, product code OTE, which are postamendments class III devices, from class III (premarket approval) into class II (special controls), subject to premarket notification. FDA is also proposing a new device classification regulation with the name "Digital Breast Tomosynthesis System," to identify these devices along with special controls that FDA believes are necessary to provide a reasonable assurance of the safety and effectiveness of these devices.

DATES: Either electronic or written comments on the proposed order must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Please see section X of this document for the proposed effective date when the new requirements apply and for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2026-N-7630 for "Radiology Devices; Reclassification of Digital Breast Tomosynthesis System." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and,

except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents, the plain language summary of the proposed order of not more than 100 words consistent with the "Providing Accountability Through Transparency Act," or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Yanna Kang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3544, Silver Spring, MD 20993-0002, 301-796-6704, Yanna.Kang@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) establishes three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of the safety and effectiveness of the device; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act).

Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, and for which there is sufficient information to establish special controls to provide such assurance, including the issuance of performance standards, postmarket surveillance, patient registries, development and

dissemination of guidelines, recommendations, and other appropriate actions FDA (the Agency or we) deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act).

Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Devices that were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, (generally referred to as "postamendments devices") are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require approval of a premarket approval application (PMA) unless, and until: (1) FDA reclassifies the device into class I or II, or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C 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 FD&C Act (21 U.S.C. 360(k)) and part 807, subpart E, of the regulations (21 CFR part 807, subpart E).

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use.[1]

[1] See generally section 513 of the FD&C Act.

FDA relies upon "valid scientific evidence," as stated in section 513(a)(3) of the FD&C Act and defined in 21 CFR 860.7(c)(2), in the classification process to determine the level of regulation for devices.[2] In general, to be considered in the reclassification process, the "valid scientific evidence" upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending PMA (see section 520(c) of the FD&C Act). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of the device, but it does not include descriptions of methods of manufacture and product composition and other trade secrets.

In accordance with section 513(f)(3) of the FD&C Act, FDA is issuing this proposed order to reclassify DBT systems intended to generate digital cross-sectional x-ray images of the breast that can be used for the screening and diagnosis of breast cancer for prescription use only (product code OTE),[3] which are postamendments class III devices, into class II (special controls), subject to premarket notification, because FDA believes the standard in section 513(a)(1)(B) of the FD&C Act is met as general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of these devices, and there is sufficient information to establish special controls, which, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of these devices.[4]

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[2] See generally *id*.

[3] FDA's Center for Devices and Radiological Health (CDRH) uses product codes to assist in accurate identification and tracking of current medical devices and to allow for tracking of and easy reference to predicate device types. A product code consists of a three-letter combination which associates a device's type with a product classification designated for the application. The three-digit classification product codes in CDRH's Product Classification Database carry no other significance. See FDA's guidance titled "Medical Device Classification Product Codes", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-classification-product-codes-guidance-industry-and-food-and-drug-administration-staff.

[4] FDA notes that the ACTION caption for this proposed order is styled as "Proposed amendment; proposed order; request for comments" rather than "Proposed order." Beginning in December 2019 this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

Based on the PMA data available to FDA in accordance with section 520(h)(4) of the FD&C Act,[5,6] associated Panel deliberations, published peer-reviewed literature, and data available to the Agency demonstrating a lack of significant postmarket safety signals, FDA believes there is sufficient information to reclassify these devices from class III (premarket approval) into class II (special controls). Therefore, FDA is proposing to establish a new device classification regulation, "Digital Breast Tomosynthesis System" and classify this device type into class II along with the special controls that the Agency believes are necessary to provide a reasonable assurance of the safety and effectiveness of these devices.

Under the FD&C Act, premarket notification (510(k)) submissions are required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt from 510(k) requirements under section 510(m) of the FD&C Act.[7] FDA has not made this determination for DBT systems, and therefore, FDA is not proposing that this class II device type be exempt from the 510(k) requirements. If this proposed order is finalized, persons who intend to market a DBT system must submit to FDA a premarket notification under section 510(k) of the FD&C Act and receive clearance prior to marketing the device.

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[5] In proposing to reclassify DBT systems from class III to class II, FDA, on its own initiative, is relying on data from relevant PMAs and a relevant PMA panel-track supplement, available to FDA with product code OTE, in accordance with the six-year rule. See section 520(h)(4) of the FD&C Act; see also, FDA guidance titled "Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997--Guidance for Industry and for FDA Reviewers," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-section-216-food-and-drug-administration-modernization-act-1997-guidance-industry-and-fda. The data for this specific proposed reclassification was from relevant PMAs and a PMA panel-track supplement approved after November 28, 1990, and before January 11, 2020, as noted in section II of this proposed order. See also, FDA's premarket approval database, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.

[6] For the purpose of this proposed order, PMA data considered in accordance with section 520(h)(4) includes only that data which was submitted to and therefore considered by FDA at the time the PMA was reviewed and approval was issued.

[7] In considering whether to exempt class II devices from premarket notification, FDA considers whether premarket notification for the type of device is necessary to provide reasonable assurance of safety and effectiveness of the device. FDA generally considers the factors initially identified in the January 21, 1998, *Federal Register* notice (63 FR 3142) and further explained in FDA's guidance issued on February 19, 1998, titled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff" in determining whether premarket notification is necessary for class II devices. FDA also considers that, even when exempting devices from the 510(k) requirements, these devices would still be subject to certain limitations on exemptions, for example, the general limitations set forth in 21 CFR 892.9.

II. Regulatory History of the Device

In accordance with section 513(f)(1) of the FD&C Act, DBT systems are automatically classified into class III because they were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, have not been reclassified into class I or II, and have not been found substantially equivalent to a device placed in commercial distribution after May 28, 1976, which was subsequently classified or reclassified into class II or class I. Therefore, these devices are subject to the PMA requirements under section 515 of the FD&C Act (21 U.S.C. 360e).

The proposed reclassification applies to DBT systems that are prescription use devices (product code OTE) intended to generate digital cross-sectional x-ray images of the breast that can be used for the screening and diagnosis of breast cancer. As discussed further below, FDA approved the first DBT system on February 11, 2011(Refs. 1 and 2). Since the first approval order for a DBT system, FDA has reviewed and approved 3 additional original PMAs (P130020 (Ref. 3), P140011 (Ref. 4), P160031 (Ref. 5)) and 26 PMA supplements, including 1 panel-track supplement (P080003/S001 (Ref. 6)), under product code OTE. In accordance with the "six-year rule" described in section 520(h)(4) of the FD&C Act (21 U.S.C. 360j(h)(4)), FDA considered data contained in each of the original PMAs as well as the panel-track supplement[8] as part of the evidence being relied upon[9] to support the proposed reclassification from class III to II.

While the DBT systems that are the subject of the four original PMAs have unique attributes in certain respects (e.g., angular span), FDA has determined that these DBT systems have sufficiently similar purposes, design considerations, functions, and other features related to safety and effectiveness such that the information and data reviewed and analysis conducted by

[8] The term "panel-track supplement" is defined in section 737(4)(B) of the FD&C Act, as, "a supplement to an approved premarket application or premarket report under section 515 that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness."

[9] In accordance with section 520(h)(4) of the FD&C Act, FDA has not relied on information in PMA supplements approved within the last 6 years to develop the proposed special controls or to otherwise inform this proposed reclassification action.

FDA was analogous across all applications available to the Agency. As such, and to avoid redundancy, the summaries below are intended to provide examples that are representative of the PMA information and data that was reviewed and considered by FDA across the applications in proposing to reclassify DBT systems from class III (premarket approval) into class II (special controls).

On January 22, 2008, FDA filed an original PMA (P080003 (Ref. 1)) for the Selenia Dimensions 3D system from Hologic, Inc. The Radiological Devices Panel (the "Panel") met on September 24, 2010, and deliberated on the Selenia Dimensions 3D system PMA (Ref. 2) and the Panel's consensus was that the benefits of the device outweighed the risks for the proposed indications. On February 11, 2011, FDA approved the original PMA for the Selenia Dimensions 3D system, the first DBT system to obtain premarket approval (Ref. 1). The Selenia Dimensions 3D system is intended for use in the same clinical applications as full field digital mammography (FFDM). The system can be used to generate both a two-dimensional (2D) FFDM image set and a three-dimensional (3D) DBT image set and the screening examination is intended to consist of a 2D FFDM image set plus a 3D DBT image set.

On October 22, 2012, FDA filed a panel-track supplement to the original PMA (P080003/S001 (Ref. 6)) seeking to expand the indications for use for the Selenia Dimensions 3D system with C-View Software Module to include the capability to generate synthesized 2D views as an alternative to 2D FFDM views to be reviewed along with DBT images, thereby reducing the cumulative radiation exposure for a screening exam. The Panel met again on October 24, 2012 (Ref. 7), to review the panel-track PMA supplement, and the consensus of the Panel (with no Panel members abstaining) was that the benefits outweigh the risks of the Selenia Dimensions 3D System with C-View Software Module (synthetic 2D or s2D) for the proposed indications for use. The single dissent from one Panel member was due to concerns with the generalizability of the clinical study results in support of the proposed indication for use given the study design and specific study exclusions (patients with large breasts, implants, or tissue

markers). As further elaborated in section VI, which discusses the use and adoption of this technology since these approvals, FDA believes that the concerns expressed by the dissenting Panel member have been addressed as a result of the significant amount of subsequently generated data demonstrating the safety and effectiveness of DBT systems with the capability to generate synthetic 2D images.

Based on a search of FDA's Medical Device Recalls database using product code OTE, as of July 21, 2026 FDA has received no Class III recalls, five Class II recalls, and no Class I recalls[10] for DBT systems. Of the Class II recalls, one was due to potential errors in image reconstruction in cases where breasts with a thickness greater than 90 mm covered nearly the entire detector surface, one was due to the potential that unexpected movement by the c-arm might cause blunt trauma should the tube arm impinge upon an individual, one was due to a software issue that may impact image quality when the device is used in certain modalities, one was due to an unapproved slabbing software function enabled for use, and one was due to systems developing loose, missing, or broken internal bolts over time. No injuries have been reported as a result of these recalls. Based on a search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database using product code OTE, as of July 21, 2026 FDA has received 968 Medical Device Reports (MDRs). While this represents a notable volume of reports, the majority of the MDRs reported indicated no known impact or consequence to patient, no patient involvement, and/or no clinical signs, symptoms, or conditions. Moreover, the majority of MDRs documented straightforward resolutions to identified problems, such as replacing a part or tightening loose hardware. About 1 percent of these MDRs reported serious injury attributed to the use of the device, but not necessarily caused by the device (e.g., a technologist operating the device slipped and twisted an ankle). FDA's analysis of these MDRs, in conjunction with the identified risks to health, demonstrates that the reported adverse events

[10] Class I, II, and III recalls are defined in 21 CFR 7.3(m).

align with known risk categories and can be effectively addressed with special controls to provide a reasonable assurance of the safety and effectiveness of DBT systems.

III. Device Description

DBT systems are postamendments devices classified into class III under section 513(f)(1) of the FD&C Act. DBT systems are prescription devices that are intended to generate digital cross-sectional x-ray images of the breast that can be used for the screening and diagnosis of breast cancer. DBT systems may include various components, such as acquisition hardware, x-ray tube, x-ray generator, breast compression system and software, digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment support devices, and other components. The device acquires 2D projection images by moving the tube head in a specific limited angular arc over the stationary compressed breast capturing multiple images at multiple angles during a short scan. These individual images are then reconstructed into a series of thin slices that can be displayed on a workstation. DBT systems enable generating 2D and 3D images, separately or combined under a single compression. Additionally, 2D images or slabs may be synthesized from the 3D images for viewing along with the original images.

In addition, DBT is considered a mammographic modality under the Mammography Quality Standards Act (MQSA) (Pub. L. No. 102-539), and facilities that perform mammography using DBT systems are subject to MQSA requirements.[11] The MQSA regulations define a mammographic modality as "a technology […] for radiography of the breast."[12]

IV. Proposed Reclassification and Summary of Reasons for Reclassification

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[11] *See* Mammography Quality Standards Act of 1992, Pub. L. No. 102-539, codified at 42 U.S.C. 263b (MQSA), enacted on October 27, 1992; see also 21 CFR 900.2(z). Congress enacted MQSA to ensure that all people have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. Following enactment of the law, FDA developed and implemented MQSA regulations, the most recent version of which went into effect on September 10, 2024, available at https://www.federalregister.gov/documents/2023/03/10/2023-04550/mammography-quality-standards-act. FDA also issued the Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide on August 26, 2024, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/mammography-quality-standards-act-and-regulation-amendments-small-entity-compliance-guide.

[12] 21 C.F.R. 900.2(z).

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify DBT systems, which are postamendments devices, from class III into class II, subject to premarket notification (510(k)) requirements under section 510(k) of the FD&C Act. FDA believes that there is sufficient data and information available to the Agency through the data and information provided in original PMAs and one panel-track supplement that may be considered under section 520(h)(4) of the FD&C Act (Refs. 1 and 3 to 6), associated Panel deliberations (Refs. 2 and 7), published peer-reviewed literature (Refs. 8 to 10), FDA's MAUDE database, and the Medical Device Recalls database to establish special controls. More specifically, in evaluating these data sources, FDA has identified the risks to health for inclusion in the overall risk assessment of DBT systems and is proposing special controls that include mitigation measures for each of the risks to health identified in section V. FDA believes that these special controls, together with general controls, would effectively mitigate the risks to health identified in section V and are necessary to provide a reasonable assurance of safety and effectiveness of these devices. The Agency does not believe that the general controls applicable to the devices are sufficient to effectively mitigate the risks to health identified for these devices, and therefore, does not believe that the general controls applicable to the devices are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

FDA is proposing to revise 21 CFR part 892 to create a new device classification regulation with the name "Digital Breast Tomosynthesis System." DBT systems are intended for the generation of digital cross-sectional x-ray images of the breast that can be used for the screening and diagnosis of breast cancer. Under this proposed order, if finalized, DBT systems will be identified as intended for prescription use. Prescription use devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and § 801.5 (21 CFR 801.5), if the conditions of § 801.109 are met.

Under the FD&C Act, 510(k) submissions are required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt from 510(k) requirements under section 510(m) of the FD&C Act.[13] FDA has not made this determination for DBT systems, and therefore, FDA is not proposing this class II device type be exempt from 510(k) requirements. If this proposed order is finalized, persons who intend to market a DBT system will need to submit to FDA a 510(k) and receive clearance prior to marketing the device.

This proposed order does not apply to FFDM systems, which FDA has previously classified under 21 CFR 892.1715. FFDM systems are in class II (special controls)[14] under their respective classification regulation, in addition to general controls. Further, this proposed order does not apply to other cross-sectional mammographic x-ray systems, such as Dedicated Breast Computed Tomography System[15], which remains a class III device.

This proposed order, if finalized, will decrease regulatory burden on industry, as manufacturers will no longer have to submit a PMA for these types of devices but can instead submit a 510(k) to the Agency for review prior to marketing their device. The 510(k) pathway is less burdensome and generally more cost-effective for industry and FDA than the PMA pathway, the most stringent type of device marketing application required by FDA. A 510(k) typically results in a shorter premarket review timeline compared to a PMA, which ultimately may provide more timely patient access for these types of devices. FDA expects that the reclassification of these devices would enable more manufacturers to develop these types of

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[13] See *supra* note 7.

[14] The special controls for FFDM systems can be found in FDA's special control guidance titled "Full-Field Digital Mammography System--Class II Special Controls" (FFDM Guidance), available at https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/full-field-digital-mammography-system-class-ii-special-controls-guidance-industry-and-fda-staff.

[15] A dedicated breast computed tomography system is a cross-sectional mammographic x-ray system that is generally regarded as a different modality than DBT by clinicians. Unlike a DBT system, which is intended for screening and diagnosis of breast cancer, this device is intended for diagnostic purposes only under product code OLQ.

devices such that patients would benefit from increased access to appropriately safe and effective devices.

Additionally, manufacturers may wish to use predetermined change control plans (PCCPs) to implement future modifications to their devices without needing to submit a new 510(k) for each significant change or modification[16] while continuing to provide a reasonable assurance of device safety and effectiveness.[17] FDA reviews a PCCP as part of a marketing submission for a device to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for implementing each modification described in the PCCP. When used appropriately, PCCPs authorized by FDA are expected to be least burdensome for manufacturers and FDA.[18]

V. Risks to Health

After consideration of FDA's accumulated experience with these devices from review of the data and information provided in each DBT system original PMA and a panel-track supplement that may be considered under section 520(h)(4) of the FD&C Act (Refs. 1 and 3 to 6), associated Panel deliberations (Refs. 2 and 7), published peer-reviewed literature (Refs. 8 to 10), FDA's MAUDE database, and the Medical Device Recalls database, FDA has identified the following probable risks to health associated with a DBT system:

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[16] For the purpose of this proposed order reference to "modification" means a significant change or modification that would generally require a new premarket notification under 21 CFR 807.81(a)(3). For additional details, see FDA guidances titled "Deciding When to Submit a 510(k) for a Change to an Existing Device," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device.

[17] Section 3308 of the Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 (FDORA), enacted on December 29, 2022, added section 515C "Predetermined Change Control Plans for Devices" to the FD&C Act. Section 515C has provisions regarding predetermined change control plans (PCCPs) for devices requiring premarket approval or premarket notification. Under section 515C, supplemental applications (section 515C(a)) and new premarket notifications (section 515C(b)) are not required for a change to a device that would otherwise require a premarket approval supplement or new premarket notification if the change is consistent with a PCCP approved or cleared by FDA.

[18] Sections 513 and 515 of the FD&C Act. See also, FDA's guidance titled "The Least Burdensome Provisions: Concept and Principles," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.

(1) *Corrupted or non-diagnostic images*. Incorrect or delayed diagnosis and treatment, as well as repeated x-ray radiation exposure could occur if the images are corrupted or otherwise not sufficient for diagnostic purposes.

(2) *Failure to interpret the images correctly*. If a user cannot interpret the images correctly due to poor image quality, false positive or false negative diagnoses may result. False negative results could result in complications, including incorrect or delayed diagnosis of cancer and treatment; false positive results may result in complications, such as incorrect management of the patient with possible adverse effects, and unnecessary additional imaging and/or invasive procedures, such as biopsy or unnecessary x-ray radiation exposure, as well as patient anxiety.

(3) *Inadequate breast coverage*. Incorrect or delayed diagnosis and treatment, as well as repeated x-ray radiation exposure could result from an incomplete image that does not include all areas of the breast.

(4) *Inappropriate breast compression*. When the breast is compressed with too much, or not enough, force and/or is not positioned properly, patient motion, reduced image quality, reduced lesion conspicuity, and inappropriate radiation exposure may result. Consequently, incorrect or delayed diagnosis and treatment, as well as repeated x-ray radiation exposure may occur.

(5) *Device failure or malfunction*. The absence or delay of device output, or incorrect device output, leading to inaccurate patient assessment and incorrect or delayed diagnosis and treatment, as well as repeated x-ray radiation exposure, could result from a device failure or malfunction. Additionally, electrical, thermal, or mechanical injury may occur if, while in operation, the device discharges electricity that could shock the user or patient; electrical discharges or exposure to device-generated heat may cause thermal injury or discomfort; and moving parts may cause mechanical injury.

(6) *Use error or improper use of the device*. Use of the device with inappropriate image acquisition parameters, or to process images acquired with incompatible imaging hardware or

with incompatible software, could result in incorrect or delayed diagnosis and treatment, as well as repeated x-ray radiation exposure.

(7) *Excessive x-ray exposure*. Acute health effects such as erythema (skin reddening) and epilation (hair loss) can result from excessive x-ray exposure.

(8) *Interference with other devices*. The device or nearby devices could fail to function as intended due to interference caused by components of the device. Individuals with electrically powered implants could experience an adverse interaction with the device due to electromagnetic interference or radiofrequency interference.

(9) *Adverse tissue reaction.* A patient could experience skin irritation and/or allergic reaction associated with the use and operation of the device via the use of non-biocompatible materials in patient-contacting components of the device.

(10) *Infection*. If validated methods and instructions for reprocessing (i.e., cleaning or disinfecting between uses, as necessary) of any reusable components as provided in the labeling are not followed, the device may introduce pathogenic organisms to patients which may result in infection.

VI. Summary of Data Upon Which Reclassification Is Based

The safety and effectiveness of this device type have become well established since the initial approval of the first DBT system in 2011. FDA believes that DBT systems (product code OTE) should be reclassified from class III (premarket approval) into class II (special controls) on the basis that special controls, in addition to general controls, can be established to mitigate the risks to health identified in section V and there is sufficient information to establish special controls, which, in addition to general controls, would provide a reasonable assurance of the safety and effectiveness of these devices. The proposed special controls are identified by FDA in section VII of this proposed order.

Taking into account the available evidence and the nature and known incidence of the risks to health of the devices, FDA, on its own initiative, is proposing to reclassify these

postamendments class III devices into class II. FDA's reasons for reclassification are based on the scientific and clinical information available. As noted earlier, the safety and effectiveness of this device type have become well established since the initial approval of the first DBT system in 2011. The Agency has gained considerable experience with DBT in the last decade and has considered and analyzed the data from four original PMAs and one PMA panel-track supplement for DBT systems available to FDA in accordance with section 520(h)(4) of the FD&C Act. Further, there have been many advancements in the field in terms of clinical research and adoption of DBT systems as well as the development of standards, including recognized consensus standards and guidelines (Refs. 11 to 17), which serve as important factors in shaping the Agency's knowledge and confidence about this technology.[19] As such, the nature of the associated risks to health is known, and special controls can be established to sufficiently mitigate these risks.

As reported in the medical literature, clinical studies evaluating millions of women have been performed to analyze the performance of DBT systems (Refs. 8 to 10). One of the largest systematic meta-analysis studies to date (Ref. 8) recently compared the performance of (a) FFDM, (b) DBT alone, (c) combined use of DBT and FFDM, and (d) combined use of DBT and s2D. This meta-analysis analyzed 42 published studies covering 2,606,269 patients with 13,003 cases of breast cancer. The key metrics studied were cancer detection rate (CDR), invasive cancer detection rate (iCDR), recall rate, and positive predictive value (PPV1). Findings suggested that combined DBT and FFDM (6.36/1000) and combined DBT and s2D (7.40/1000) had significantly higher CDRs than FFDM alone (4.68/1000). DBT alone (5.20/1000) was not significantly different from FFDM alone. Combined DBT and FFDM (4.53/1000) and combined

[19] Section 514(c) of the FD&C Act states, in part, that FDA "shall, by publication in the *Federal Register* . . . recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement." More information can be found in FDA's guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

DBT and s2D (5.68/1000) had significantly higher iCDRs than FFDM alone (3.42/1000). DBT alone (3.68/1000) was not significantly different from FFDM alone. The recall rate was lowest in combined DBT and s2D (42.3/1000) compared to FFDM alone (78.8/1000). No significant difference was observed for DBT alone (82.4/1000) or combined DBT and FFDM (64.6/1000) compared to FFDM alone. Positive predictive value (PPV1) was observed to be highest in combined DBT and s2D (16.0%) and combined DBT and FFDM (10.0%), compared to FFDM alone (7.0%). DBT alone (7.0%) showed no improvement over FFDM alone.

This meta-analysis concluded that DBT combined with FFDM or s2D improves cancer detection and reduces recall rates. Furthermore, the data showed that s2D with DBT is preferred over combined DBT and FFDM because it maintains diagnostic performance while reducing radiation dose and costs. The meta-analysis demonstrates that DBT systems perform at least as effectively as FFDM systems across all key performance metrics--CDR, iCDR, recall rate, and positive predictive value--with no statistically significant differences observed.

FFDM systems with similar performance characteristics and similar risks to health as DBT systems are currently regulated as class II devices with special controls and have been without any significant safety signals since 2010. FDA believes this further supports the reclassification of DBT systems into class II and specifically supports a determination that there is sufficient information to establish special controls that, in addition to general controls, will provide a reasonable assurance of safety and effectiveness. The additional finding that DBT combined with s2D provides superior performance to FFDM alone further supports that DBT systems, when subject to appropriate special controls, will continue to provide appropriately safe and effective breast cancer screening. The extensive evidence base--encompassing more than 2.6 million patients across 42 studies--provides sufficient data to support the proposed reclassification of DBT systems.

Further, FDA publishes the most commonly requested national statistics regarding the MQSA program at a recurring cadence.[20] Based on the statistics as of July 8, 2026, out of the 9,107 certified facilities in the United States, 94 percent have DBT units, and 95 percent of the accredited digital 2D units within those facilities are also accredited DBT units. As noted in section II, there remains an absence of any major safety issues in postmarket data despite wide adoption, which increases FDA's confidence that special controls, in addition to general controls, are sufficient to ensure the safety and effectiveness of DBT systems.

The MQSA regulations established specific quality control (QC) testing methodologies for every mammography system in the United States. A number of national and international professional associations, in addition to DBT system manufacturers, have now developed QC manuals that provide uniform test procedures, performance criteria, and minimum test frequencies that may be useful to manufacturers and users of DBT systems in evaluating and maintaining the performance of the device (Refs. 16 and 17). FDA's experience with the utility of these QC manuals in evaluating and maintaining the performance of the device provides additional confidence that special controls can be established to provide a reasonable assurance of safety and effectiveness of these devices.

There has also been significant development in the methods and tools used for assessing performance of DBT systems since the first DBT system was approved by FDA in 2011. The increasing availability and confidence in such evaluation methods and tools support FDA's determination that special controls, in addition to general controls, are sufficient to provide a reasonable assurance of the safety and effectiveness of DBT systems. Image quality measurements are essential for evaluating whether DBT systems are adequately safe and effective. There is now a rich body of scientific literature describing testing methods for objectively assessing the image quality of DBT systems for both the physical testing (Refs. 18

[20] The published MQSA statistics can be found at https://www.fda.gov/radiation-emitting-products/mammography-information-patients/mqsa-national-statistics.

and 19), as well as in silico testing (Refs. 20 to 23). Multiple workshops and special sessions have been held at scientific conferences throughout the world to discuss these methods to evaluate parameters of safety and effectiveness.

In November 2018 FDA held a symposium titled "Objective Assessment of Digital Breast Tomosynthesis Image Quality Using Anthropomorphic Phantoms." During this one-day technical symposium, scientists from FDA and other institutions discussed different approaches for assessing the image quality of DBT systems. The focus was on objective, task-based performance assessment of DBT systems using anthropomorphic phantoms and use of human and model observer studies. Example applications of the methodologies discussed were described and have since been published in the literature (Refs. 18 to 20).

One prevailing theme that has come from these studies, workshops, and special sessions, and from FDA's symposium is that depending on system characteristics and modifications, these task-based performance studies using anthropomorphic phantoms with structured background may serve as an alternative to clinical studies (Refs.18 to 23). Such methods have been used in lieu of clinical studies in the scientific evaluation of these devices to support their safety and effectiveness, which has increased FDA's confidence in developing the special controls identified in this proposed order.

Based on our review of the information described in this proposed order, FDA has determined that special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness for DBT systems and that sufficient information exists to establish such special controls. Therefore, FDA, on its own initiative, is proposing to reclassify DBT systems from class III (premarket approval) into class II (special controls), subject to premarket notification (510(k)) requirements.

VII. Proposed Special Controls

FDA believes that DBT systems can be reclassified into class II with the establishment of special controls. The Agency believes that the following proposed special controls, together with

general controls, would provide reasonable assurance of the safety and effectiveness of DBT systems intended to generate digital cross-sectional x-ray images of the breast that can be used for the screening and diagnosis of breast cancer for prescription use only. Table 1 demonstrates how FDA believes the proposed special controls would mitigate each of the risks to health identified in section V.[21]

- The risk of corrupted or non-diagnostic images can be mitigated by special controls that require performance testing, including (1) bench testing to demonstrate the imaging characteristics of the DBT system and (2) objective task-based assessment of diagnostic accuracy of the DBT system conducted using human subjects, structured physical phantoms, in silico methodologies, or a combination of these approaches, as appropriate based on a detailed description of the system hardware and software, as well as appropriate software verification, validation, and hazard analysis. This risk can be further mitigated by special controls that require clinical image evaluation.[22] Furthermore, informing intended users in the labeling of a summary of performance testing results and clinical image evaluation can mitigate this risk.
    - Examples of bench tests that may be used to demonstrate the imaging characteristics of a DBT system and mitigate this risk to health include (see Refs. 11 to 13 for more detail on recognized consensus standard methods for performing these tests):

[21] FDA believes it would be beneficial for sponsors that would like more information about how to comply with the special controls and mitigate the risks to health posed by DBT systems to submit a Pre-Submission with a detailed description of the proposed system hardware and software to discuss the testing plans with FDA. Additional information may be found in FDA's guidance on Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

[22] Separately from the requirements of the special controls, physicians performing DBT clinical image evaluations must be qualified under MQSA to interpret mammography exams. (See 21 CFR 900.12 for requirements under the MQSA relating to qualifications of interpreting physicians). FDA also recommends that physicians performing DBT evaluations (i) be certified by the American Board of Radiology, American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada; (ii) have at least 5 years' experience following residency in diagnostic radiology with at least 50 percent of each year's practice in breast imaging and have had training in clinical image quality equivalent to that provided by the FDA-approved accreditation bodies; and (iii) be currently using a DBT system at an MQSA or VAH-certified facility.

- Spatial Resolution,
- Noise Analysis,
- Signal-to-Noise Ratio transfer--Detective Quantum Efficiency (DQE),
- Detector Lag,
- Automatic Exposure Control (AEC) Performance,
- Geometric Distortion,
- Missed tissue at top and bottom of reconstructed DBT volume,
- Missed tissue at chest wall side in reconstructed DBT volume,
- Testing of Alignment and Collimation, and
- Radiation Dosimetry.

- Objective task-based assessment of diagnostic accuracy can be conducted through one or more of the following methodologies to mitigate this risk to health:
  - Reader study with human subjects, defined as a study in which readers review and interpret patient images acquired from a DBT system for a specified task, and task performance of the readers is measured to evaluate the effectiveness of the DBT system.
  - Observer study with structured physical phantoms, defined as an objective task-based assessment of performance for the DBT system using structured phantoms similar to published methods described in the literature (Refs. 18 and 19).
  - In silico Trials (IST) also referred to as Virtual Clinical Trials (VCT), defined as a study to provide estimates of the performance of a DBT system based on computational modeling in a virtual population for a clinical task of interest and within a specific context of use (Refs. 20 to 24).

- The risk of failure to interpret the images correctly due to poor image quality (the risk of false positive and false negative results) can be mitigated by special controls that require demonstrating the performance characteristics of the device across a representative range of settings in screening and diagnosis of breast cancer. The device can be evaluated using performance testing, which includes bench testing and objective task-based assessment of diagnostic accuracy of the DBT system, as previously described, to mitigate the risk to health of "corrupted or non-diagnostic images." This risk can be further mitigated by special controls that require clinical image evaluation. Informing intended users in the labeling of a description of the qualifications and/or clinical training needed for the safe use of the device and a summary of performance testing results and clinical image evaluation can further mitigate this risk.
- The risk of inadequate breast coverage can be mitigated by special controls that require some elements of performance testing, specifically bench testing[23] to demonstrate the imaging characteristics of the DBT system as well as clinical image evaluation. This risk can be further mitigated with a description of the qualifications and/or clinical training needed for the safe use of the device and a summary of performance testing and clinical image evaluation in the labeling.
- The risk of inappropriate breast compression can be mitigated by special controls that require some elements of performance testing, specifically bench testing[24] to demonstrate the imaging characteristics of the DBT system, and software verification, validation, and hazard analysis, and clinical image evaluation. This risk can be further mitigated with a description of the qualifications and/or clinical training needed for the safe use of the

[23] The following bench tests may generally be appropriate in addressing this special control: missed tissue at top and bottom of reconstructed DBT volume, missed tissue at chest wall side in reconstructed DBT volume, and alignment and collimation.
[24] The following bench tests may generally be appropriate in addressing this special control: missed tissue at chest wall side in reconstructed DBT volume and AEC performance.

device and a summary of performance testing and clinical image evaluation in the labeling.

- The risk of device failure or malfunction can be mitigated by special controls that require some elements of performance testing, specifically bench testing, to demonstrate the imaging characteristics of the DBT system, appropriate software verification, validation, and hazard analysis, and electrical safety/electromagnetic compatibility (EMC) testing. Additionally, this risk can be further mitigated with quality control testing recommendations in the labeling.
- The risk of use error or improper device use can be mitigated by special controls that require appropriate software verification, validation, and hazard analysis as well as a detailed description of the device and its outputs and a description of the qualifications and/or clinical training needed for the safe use of the device in the labeling.
- The risk of excessive x-ray radiation exposure can be mitigated by special controls that require some elements of performance testing, specifically bench testing[25] to demonstrate the imaging characteristics of the DBT system as well as appropriate software verification, validation, and hazard analysis and electrical safety/EMC testing. This risk can be further mitigated with a description of the qualifications and/or clinical training needed for the safe use of the device in the labeling.
- The risk of device failure to function as intended due to interference with other devices due to radiofrequency or electromagnetic interference can be mitigated by special controls requiring testing that demonstrates EMC.
- The risk of adverse tissue reaction for patient-contacting components can be mitigated by special controls requiring that components of the device that may contact the patient be demonstrated to be biocompatible.

[25] The following bench tests may generally be appropriate in addressing this special control: DQE, AEC performance, alignment and collimation, and radiation dosimetry.

- The risk of infection from patient-contacting devices can be mitigated by special controls that require labeling that includes validated instructions for cleaning and disinfecting equipment surfaces that contact the patient.

Table 1.--Risks to Health and Mitigation Measures for a DBT System

Identified Risks to Health	Mitigation Measures
Corrupted or non-diagnostic images	Performance testing Software verification, validation, and hazard analysis Clinical image evaluation Labeling
Failure to interpret the images correctly, leading to false negative or false positive results	Performance testing Clinical image evaluation Labeling
Inadequate breast coverage	Performance testing Clinical image evaluation Labeling
Inappropriate breast compression	Performance testing Software verification, validation, and hazard analysis Clinical image evaluation Labeling
Device failure or malfunction	Performance testing Software verification, validation, and hazard analysis Electrical safety/EMC testing Labeling
Use error/improper use of the device	Software verification, validation, and hazard analysis Labeling
Excessive x-ray radiation exposure	Performance testing Software verification, validation, and hazard analysis Electrical safety/EMC testing Labeling
Device or nearby devices failure to function as intended due to interference	Electrical safety/EMC testing
Adverse tissue reaction	Biocompatibility evaluation
Infection	Labeling

If this proposed order is finalized, DBT systems will be reclassified into class II (special controls) and will be subject to premarket notification requirements under section 510(k) of the FD&C Act. As discussed in this proposed order, the intent is for the reclassification to be codified in the new classification regulation 21 CFR 892.1717. If finalized, DBT systems will be required to comply with the particular mitigation measures set forth in the special controls. In addition, FDA is proposing that these devices be for prescription use only. Prescription devices

are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and § 801.5, as long as the conditions of § 801.109 are met. Adherence to the proposed special controls, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of the devices.

VIII. Analysis of 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.

IX. Paperwork Reduction Act of 1995

While this proposed order contains no new collections of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 820 (Quality Management System Regulation) have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 807, subpart E (Premarket Notification Procedures) have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 801 (Device Labeling) have been approved under OMB control number 0910-0485; and the collections of information in 21 CFR part 814, subparts A through E (Premarket Approval (PMA) of Medical Devices) have been approved under OMB control number 0910-0231.

X. Proposed Effective Date

FDA proposes that any final order based on this proposed order become effective 30 days after its date of publication in the *Federal Register*.

XI. Codification of Orders

Under section 513(f)(3) of the FD&C Act, FDA may issue final orders to reclassify devices. FDA will continue to codify classifications and reclassifications in the Code of Federal

Regulations (CFR). Changes resulting from final orders will appear in the CFR as newly codified orders. Therefore, under section 513(f)(3) of the FD&C Act, in the proposed order, we are proposing to codify digital breast tomosynthesis system in the new 21 CFR 892.1717, under which DBT systems would be reclassified from class III into class II.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA has verified the website addresses as of the date this document publishes in the *Federal Register*, websites are subject to change over time.

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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 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, 360*l*, 371.

2. Add § 892.1717 to subpart B to read as follows:

§ 892.1717 Digital breast tomosynthesis system.

(a) *Identification.* A digital breast tomosynthesis system is a prescription device that is intended to generate digital cross-sectional x-ray images of the breast that can be used for the screening and diagnosis of breast cancer. This device may include acquisition hardware and software, digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, compression system, patient and equipment support devices, and components.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Performance testing data must include:

(i) Data to demonstrate the performance characteristics of the device across a representative range of settings in screening and diagnosis of breast cancer through the following:

(A) Bench testing to demonstrate the imaging characteristics of the device and associated radiation dose levels.

(B) Objective task-based assessment of diagnostic accuracy of the device, conducted using human subjects, structured physical phantoms, or in silico methodologies, or a combination of these approaches.

(ii) Detailed description of the system hardware and software, which includes acquisition hardware and software, image receptor, acquisition workstation, automatic exposure control,

image processing and reconstruction programs, patient and equipment supports, component parts, and accessories.

(2) Clinical image evaluation data must demonstrate the images are of sufficiently acceptable quality for screening and diagnosis of breast cancer.

(3) Software verification, validation, and hazard analysis must be performed.

(4) Data must demonstrate the electrical safety, mechanical safety, thermal safety, and electromagnetic compatibility (EMC) of the device in the intended use environment.

(5) Patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Labeling must include the following:

(i) A detailed device description including principles of operation, system hardware and software, which include acquisition hardware and software, image receptor, acquisition workstation, technique factors, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories.

(ii) A detailed description of the device outputs.

(iii) User qualifications and/or clinical training needed for the safe use of the device.

(iv) A detailed summary of the objective task-based diagnostic accuracy assessment, including test methods, dataset characteristics, results, and a summary of sub-analyses on case distributions stratified by relevant confounders.

(v) A detailed summary of bench testing results, including graphs or tables as appropriate.

(vi) A detailed summary of the clinical image evaluation performed with the device.

(vii) A description of quality control testing, including detailed procedures for performing these tests, if applicable, and the frequency of testing.

(viii) Validated methods and instructions for cleaning and disinfection of any reusable patient-contacting components.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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