510(k) Summary

JAN 29 2013

This 510(k) summary is submitted in accordance with the requirements of 21 CFR Part 807.87 (b)

Product Name: Contrast Enhanced Digital Mammography

Product Classification Name: Full Field Digital Mammography System

Product Classification Code: MUE **CFR Section:** 892.1715

Classification Panel: Radiology **Class** II

Manufacturer: Hologic, Inc.
36-37 Apple Ridge Road
Danbury, CT 06810 USA

Contact Person: Deborah Thomas
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Date Prepared: December 14, 2012

Predicate Devices:

K103485 GE Healthcare Contrast Enhanced Spectral Mammography

Device Description:

The Contrast Enhanced Digital Mammography (CEDM) Option used with the Selenia Dimensions 2D Full Field Digital Mammography System (FFDM) is an imaging option, referred to as dual energy imaging. The Selenia Dimensions was designed to support dual energy imaging. CEDM Duel Energy Subtracted Image (CEDM image) acquisition consists of two 2D images, taken in sequence and in the same breast compression. The first image is a standard 2D FFDM image, as is acquired during conventional FFDM imaging. The kVp range used is typically 25 to 33 kVp and the rhodium and silver filters are the conventional ones used in this kVp range. This is referred to as the 'low energy' image. Following the low energy acquisition, a second image is acquired. This will be referred to as the 'high energy' image, and it uses a copper filter and a kVp range of 45 to 49 kVp.

A weighted subtraction method is then used to subtract the contents of the low energy image from the high energy image. The two images are acquired in rapid succession to minimize the potential of patient motion that can create structural noise and can degrade image contrast. The low energy image together with the subtracted image is used clinically to evaluate the patient.

Indications for Use:

Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the Selenia Dimensions system. The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion.

Comparison with Predicate Devices:

The Contrast Enhanced Digital Mammography and predicate device, GE Healthcare Contrast Enhanced Spectral Mammography, K103485, have the same intended use, general configuration, principles of operation, and similar operating parameters.

Summary of Testing

Dual energy images captured, saved and/or transmitted by the Selenia Dimensions 2D FFDM conform with ACR/NEMA Digital Imaging Communications in Medicine version 3.0.

Hologic successfully performed design control verification and validation tests in accordance with 21 CFR Part 820.

Conclusion

The Contrast Enhanced Digital Mammography imaging option design, operation, construction and materials are similar to the existing marketed predicate device with no additional risks or hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 29, 2013

Hologic, Inc.
% Ms. Deborah Thomas
Senior Regulatory Specialist
35 Crosby Drive
BEDFORD MA 01730

Re: K123873
Trade/Device Name: Contrast Enhanced Digital Mammography (CEDM)
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: December 14, 2012
Received: December 18, 2012

Dear Ms. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K123873**

Device Name: **Contrast Enhanced Digital Mammography**

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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