**510(k) Summary**

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: 11/23/2010

Submitter: GE Healthcare
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Waukesha, WI 53188

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Device: Trade Name: Contrast Enhanced Spectral Mammography
Common/Usual Name: Full Field Digital Mammography System
Classification Names: 21 CFR 892.1715, Class II

Product Code: MUE

Predicate Device(s): Senographe DS-originally approved as P990066/S16,
Senographe Essential-originally approved as P990066/S21

Device Description: The Senographe DS and Senographe Essential are both full field digital mammography systems consisting of a digital detector, a dual track x-ray tube (molybdenum / rhodium) and an x-ray generator with control. The digital detector is a flat panel of amorphous silicon on which cesium iodide is deposited to maximize the detection of x-rays. The x-ray filter is a wheel with both a molybdenum and a rhodium filter to allow various combinations of x-ray tube track and filter when imaging breasts of different

radiological densities. The system includes a feature called Automatic Optimization of Parameters (AOP) that automatically selects the kVp, the optimal x-ray tube track and beam filtration and then terminates the exposure based on the breast density to provide consistent image quality for the user across a wide range of breast sizes and densities.

The subject of this submission is a modification that will introduce a new imaging option based on a method of image acquisition involving a x-ray exposures at two energy levels. The two exposures will be completed at the simultaneously using a technique known as "dual-energy". This x-ray acquisition methodology has been previously cleared by GE Healthcare in K013481, although that clearance excludes mammography. This Premarket Notification will implement this technology on GE Healthcare's existing Full Field Digital Mammography systems as an upgrade to existing systems, or as an option to new installations. The dual-energy exposures will be done with a single breast compression and will be following an iodine based contrast injection of an existing approved x-ray contrast agent, using the approved rate, route of administration, and dosage of the contrast agent. The new mode of operation is referred to as Contrast Enhanced Spectral Mammography (CESM) due to the nature of taking an exposure with the x-ray spectrum optimized for general mammographic imaging and a second exposure with the x-ray spectrum optimized for the iodine based contrast image. The modification also includes the implementation of an additional x-ray beam filter. The change in x-ray exposure energy, plus the change in beam filtration allow the system to optimize the x-ray spectrum for the iodine based contrast when acquiring the second exposure of the dual-energy acquisition. This filtration change is done by rotating the filter wheel and changing the beam filter selected for the high energy exposure.

These two images are combined to allow visualization of the breast tissue in a way that is typical and familiar for mammographic imaging, while being able to visualize the x-ray contrast enhancement in the breast at the same time.

Intended Use: Indications for Use:

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

Technology: The Contrast Enhanced Spectral Mammography (CESM) imaging option is a technique based on image acquisition from x-ray exposures at two different energy levels. This option utilizes a technique known as "dual-energy" which entails obtaining one exposure immediately after another. The dual energy exposures will be performed with a single breast compression and will be following an iodine based contrast injection of an existing approved x-ray contrast agent, using the approved rate, route of administration, and dosage of the contrast agent. This new mode of operation is referred to as CESM due to the concept of taking an exposure with the x-ray spectrum optimized for general mammographic imaging and a second exposure with the x-ray spectrum optimized for the iodine based contrast image.

The Contrast Enhanced Spectral Mammography Option when utilized with the Senographe DS or Senographe Essential introduces 3 main differences:

- Modifications to the control of the x-ray acquisition sequence to allow dual energy exposures.
- Modifications to the x-ray beam filter wheel to add a new filter that changes the beam characteristics during the high energy exposure.

- Modifications to the software that is used for acquisition control and for image processing to reconstruct the image for review.

Determination of Substantial Equivalence:

Contrast Enhanced Spectral Mammography when installed on a Senographe DS or Senographe Essential FFDM system delivers functionality of comparable type that is substantially equivalent to our currently marketed systems listed above and complies with the same or equivalent standards and have the same intended uses.

Summary of Non-Clinical Tests:

The Contrast Enhanced Spectral Mammography application complies with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, Contrast Enhanced Spectral Mammography, included clinical testing to quantify the effect of dual energy acquisition and CESM's contribution when compared to standard FFDM mammography and ultrasound breast imaging.

Conclusion:

GE Healthcare considers the Contrast Enhanced Spectral Mammography to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Steven Kachelmeyer
Regulatory Manager
General Electric Company
3000 N. Grandview Blvd.
WAUKESHA WI 53188

OCT - 6 2011

Re: K103485
Trade/Device Name: Contrast Enhanced Spectral Mammography
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: September 27, 2011
Received: September 29, 2011

Dear Mr. Kachelmeyer:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K103485

Device Name: Contrast Enhanced Spectral Mammography

Indications for Use:

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

Prescription Use_X_ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103485

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