DEC 2 2 2011 K110798

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

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

Date: 03/18/2011

Submitter: GE Healthcare
3000 N. Grandview Blvd
Mail Code W-709
Waukesha, WI 53188

Primary Contact Person: Steven Kachelmeyer, RAC
Regulatory Manager
GE Healthcare

Phone: 262-548-2432

Fax: 262-997-1080

Secondary Contact Person: David Blonski
X-ray Regulatory Affairs Director
GE Healthcare

Phone: 262-513-4072

Fax: 262-544-3844

Device: Trade Name: Premium View *i*
Common/Usual Name: Full Field Digital Mammography System
Classification Names: 21 CFR 892.1715, Class II

Product Code: MUE
Predicate Device(s): Senographe DS-P990066/S16,
Senographe Essential-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 will introduce a modification to a previously approved (P990066 / S015 and P990066 S020) image processing algorithm called Premium View. Premium View is an image-processing algorithm, which increases the visibility of breast structures. The main advantage is to provide a single breast image, where the contrast in the fatty tissues is similar to that obtained by setting WW (window width) and WL (window level) for optimum visualization of fatty tissues, and the contrast in the fibro-glandular tissue is similar to that obtained by setting WW and WL for optimal visualization of fibro-glandular tissues.

Premium View *i*, when utilized with the Senographe DS or Senographe Essential introduces a software change that applies different LUT values during the image processing prior to display of a very dense breast, or one with implants. 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.

Intended Use: The Senographe DS and Senographe Essential FFDM systems generate digital mammographic images that can be used for screening and in the diagnosis of breast cancer. The Senographe DS and Senographe Essential FFDM systems are intended to be used in the same clinical applications as traditional film-based mammographic systems.

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PV*i* is an option that can simplify the presentation of mammographic images, improve workflow, and streamline the review process of images with very dark or bright areas by presenting the image with the WW and WL optimized for review with minimal need for the user to make adjustments for the various tissue areas. This could be especially useful with patients who have very dense breasts, or implants that currently require multiple adjustments of WW and WL to review.

Technology: Premium View (PV) is image processing software which further improves the efficiency of the existing auto-contrast feature; it also includes a modified version of the existing Tissue Equalization (TE) processing.

Such optimization is achieved by applying different LUTs (Look Up Tables) to a high pass and low pass extractions of the image. In doing so, management of the image dynamic is achieved so that by applying PV it increases the visibility of breast structures. This is done by enhancing the contrast in glandular tissue, while preserving the visibility of the whole breast.

Premium View *i*, when utilized with the Senographe DS or Senographe Essential introduces a software change that applies different LUT values during the image processing prior to display of a very dense breast, or one with implants.

Determination of Substantial Equivalence: Premium View *i* 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 Premium View *i* option 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, Premium View *i* image processing option, included clinical testing to quantify the clinical acceptance of images that had been retrospectively processed with this image processing algorithm.

Conclusion: GE Healthcare considers the Premium View *i* option 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, RAC
Regulatory Manager
GE Healthcare
3000 N. Grandview Blvd
Mail Code W-709
WAUKESHA WI 53188

DEC 2 2 2011

Re: K110798
Trade/Device Name: Premium View i (PVi)
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: November 16, 2011
Received: November 17, 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):

Device Name: Premium View *i* (PV*i*)

Indications for Use:
The Senographe DS and Senographe Essential FFDM systems generate digital mammographic images that can be used for screening and in the diagnosis of breast cancer. The Senographe DS and Senographe Essential FFDM systems are intended to be used in the same clinical applications as traditional film-based mammographic systems.

Premium View is an image-processing algorithm, which increases the visibility of breast structures. The main advantage is to provide a single breast image, where the contrast in the fatty tissues is similar to that obtained by setting WW (window width) and WL (window level) for optimum visualization of fatty tissues, and the contrast in the fibro-glandular tissue is similar to that obtained by setting WW and WL for optimal visualization of fibro-glandular tissues.

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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)

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

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

510(k)_____

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K110798/S001