NOV 16 2012 K123174

510(k) Summary

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

Date:	October 8, 2012
Submitter:	GE Healthcare 540 West Northwest Highway Barrington, IL 60010
Primary Contact Person:	Cheryl Bork Regulatory Affairs Manager GE Healthcare Phone: 847-277-6038 Fax: 847-277-4506
Secondary Contact Person:	Jeme Wallace Regulatory Affairs Director GE Healthcare Phone: 847-277-4468 Fax: 847-939-1446
Device Trade Name:	Centricity PACS-IW with Universal Viewer
Common/Usual Name:	Picture Archiving and Communication System
Classification Names:	21 CFR 892.2050, System, Image Processing, Radiological
Product Code:	LLZ
Predicate Device:	K121387 - GE Healthcare Centricity PACS-IW
Device Description:	Centricity PACS-IW with Universal Viewer is an Internet based medical image display and interpretation software product that is part of a picture archiving and communications system. It provides users with capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images (including digital mammograms).

Device Description: (cont.)

Centricity PACS-IW with Universal Viewer includes features to access and manage medical imaging studies from Computed Tomography (CT), Magnetic Resonance (MR), Ultrasound (US), Nuclear medicine (NM), Computerized radiography (CR), Digital mammography (MG),Digital x-ray (DX), Positron Emission Tomography (PET/PT), X-Ray Angiography (XA), Digital Intra-oral X-Ray (IO), Radiofluoroscopic X-ray (RF), Secondary Capture Images (SC), Visible Light (VL) Endoscopic, Microscopic and Photographic Image Storage, Slide Coordinates Microscopic Image Storage, Presentation States (PS), Key Image Notes (KIN) and other DICOM imaging modalities.

Centricity PACS-IW with Universal Viewer is designed to be deployed over conventional TCP/IP networking infrastructure available in most healthcare organizations and utilizes commercially available computer platforms and operating systems.

The system does not produce any original medical images. All images located on the Centricity PACS, PACS-IW, and Enterprise Archive systems have been received from DICOM compliant modalities and/or image acquisition systems.

The Universal Viewer Zero Foot Print (ZFP) clinical viewer is an optional viewer which allows trained professionals to display and manipulate images stored in Centricity Enterprise Archive or other DICOM archive devices. These trained professionals include but are not limited to physicians, radiologists, nurses, medical technicians, and assistants.

The Universal Viewer Zero Foot Print option is not intended for primary diagnosis.

Intended Use: Centricity PACS-IW with Universal Viewer is a device that displays medical images (including mammograms) and data from various imaging sources. Images and data can be viewed, communicated, processed and displayed within the system or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Megapixel resolution and meet other technical specifications reviewed and accepted by the FDA.

Typical users of this system are trained professionals, including but not limited to radiologists, physicians, nurses, medical technicians, and assistants.

Technology: The Centricity PACS-IW with Universal Viewer device employs the same fundamental scientific technology as its predicate device, Centricity PACS-IW cleared under K121387, with the following modifications:

- Modified viewer to present a common unified workspace for radiologists and clinicians to perform the review, manipulation and diagnostic interpretation of images and other information generated by acquisition.
- Provides integration to Centricity PACS backend. The PACS-IW with Universal Viewer can read image data and other patient information from Centricity PACS backend.
- Implementation of a "Bookmark" feature for image display, that enables the user to capture the Display State of an exam context as it exists at any particular time, and then restores this same state at a later time.

- Enhanced hanging protocols ("smart" hanging protocols) for image display, which will assess information provided in the DICOM tags to evaluate the type of study that is being displayed to determine the most appropriate method for the study to be hung.

- Enhanced image annotations and measurements to include the ability to calculate Cardio Thoracic Ratio (CTR) (web client only) and Ellipse (ZFP only).

- Supports interface with GE Healthcare's IDI Mammo product, in place of Cedara Mammo.

- Supports interface with GE Healthcare's Advantage Workstation (AW) Server advanced visualization tools.

Technology (cont.)

- Hardware minimum specifications were modified as a result of technology advancements and obsolescence issues.

- The optional ZFP (Zero Footprint) Clinician Viewer is a non-diagnostic DICOM image and results viewer. Zero footprint:
  - image enables an EMR or other similar applications.
  - displays image data from GE Healthcare's Centricity Enterprise Archive.
  - can be accessed on a client device without requiring the user to override security settings or initiate an installation.

Centricity PACS-IW with Universal Viewer receives medical images and other information from various data sources. The information can be stored, communicated, processed and displayed within the

system or across computer networks at distributed locations, the same as its predicate devices. Centricity PACS-IW with Universal Viewer is a software-only device that runs on commercially available off-the-shelf computer hardware platforms.

The Centricity PACS-IW with Universal Viewer device will continue to have an intended use and functionality fitting within the definition of 21 CFR 892.2050, Picture Archiving and Communication Systems, Product Code LLZ.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests

The software documentation was provided at a moderate level of concern following the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Centricity PACS-IW with Universal Viewer complies with voluntary standards as detailed in this premarket notification submission. The following quality assurance measures were applied to the development of the system:

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

Summary of Clinical Tests:

The subject of this premarket notification submission, Centricity PACS-IW with Universal Viewer, did not require clinical studies to support substantial equivalence.

Conclusion: Comparison of the Intended Uses, the technological characteristics, and performance specifications demonstrate the functional equivalence of the subject device to the predicate device. Verification and Validation testing results demonstrate that no adverse effects have been introduced by these differences.

Information provided in this premarket notification submission supports the Centricity PACS-IW with Universal Viewer medical device to be as safe, as effective and substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ms. Cheryl Bork
Regulatory Affairs Manager
GE Healthcare-HCIT
540 W. Northwest Highway
BARRINGTON IL 60010

November 16, 2012

Re: K123174
Trade/Device Name: Centricity PACS-IW with Universal Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 8, 2012
Received: October 25, 2012

Dear Ms. Bork:

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 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health 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,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123174

Device Name: Centricity PACS-IW with Universal Viewer

Indications for Use:

Centricity PACS-IW with Universal Viewer is a software only product that is part of a Picture Archiving and Communication System (PACS) medical device.

Centricity PACS-IW with Universal Viewer is a device that displays medical images (including mammograms) and data from various imaging sources. Images and data can be viewed, communicated, processed and displayed within the system or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Megapixel resolution and meet other technical specifications reviewed and accepted by the FDA.

Typical users of this system are trained professionals, including but not limited to radiologists, physicians, nurses, medical technicians, and assistants.

Prescription Use __Yes___ 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)

Michael D. O'Hara

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

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