K082318

GE Healthcare
Integrated IT Solutions

Section 5: 510(k) Summary

AUG 25 2008

Submitter: GE Healthcare Dynamic Imaging Solutions
40 Boroline Road
Allendale, NJ 07401

Contact Person: Jillian M. Reed
Consultant
Reed Technical Associates, LLC

Date Prepared: August 12, 2008

Classification Name: Picture Archiving Communications System

Proprietary Name: Centricity PACS IW ™ PACS System

Predicate Devices: #K031311 Integrad*Web*™ PACS System by Dynamic Imaging, Inc.
#K042313 Integrad*Web*™ MRP/MIP™ by Dynamic Imaging, Inc.
#K072986 Integrad*Web*™ PACS System by GE Healthcare Dynamic Imaging Solutions
#K051673 Xeleris 2 Processing and Review Workstation by GE Medical Systems

Device Description:

Centricity PACS IW ™ PACS System is an Internet bases software picture archiving and communications system that provides users with capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images (including digital mammograms). Centricity PACS IW ™ PACS System includes features to access and manage medical imaging studies from cat-scan (CT), magnetic radiography (MR), ultrasound (US), nuclear medicine (NM), computerized radiography (CR), digital radiography (DR), digital mammography (DM), digital x-ray (DX), x-ray angiography (XA), PET scan (PT), and other imaging modalities. Centricity PACS IW ™ PACS System is designed to be deployed over conventional TCP/IP networking infrastructure available in most healthcare organizations and utilizes commercially available computer platforms (Intel Pentium-based) and operating systems (Microsoft Windows 2000, Windows NT, and Windows 98). The system does not produce any original medical images. All images located on Centricity PACS IW ™ PACS System have been received from DICOM compliant modalities and/or systems.

Intended Use:

Centricity PACS IW ™ PACS System by Dynamic Imaging, Inc. is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, 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 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

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

Technical Characteristics:

This device is a medical device image software that is used with computer hardware in a picture archiving and communications system user environment. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed and printed.

Substantial Equivalence:

Testing performed has shown that the Centricity PACS IW ™ PACS System incorporating enhanced PET-CT user preferences is substantially equivalent to the above referenced predicate devices.

Discussion of Non-Clinical Testing Performed:

Thorough system verification and validation testing was performed to ensure the safe and effective use of the Centricity PACS IW ™ PACS System with enhanced PET-CT user preferences.

Discussion of Clinical Testing Performed:

A reader evaluation, consisting of 11 board certified Radiologist was conducted where they evaluated the new enhanced PET-CT user preferences to the predicate device on actual clinical cases.

Conclusions:

The information provided in this special premarket notification submission has shown that the Centricity PACS IW ™ PACS System with enhanced PET-CT user preferences is substantially equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2008

GE HealthCare Dynamic Imaging System
% Ms. Jillian M. Reed
Consultant
Reed Technical Associates, LLC
25 Walnut Street
MONROE CT 06468

Re: K082318
Trade/Device Name: Centricity PACS IW™ PACS System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 12, 2008
Received: August 13, 2008

Dear Ms. Reed:

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 such 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); 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.

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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082318

Device Name: Centricity PACS IW ™ PACS System

Indications for Use:

Centricity PACS IW ™ by GE Healthcare Dynamic Imaging Solutions is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, 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 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

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

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K082318