Section 2 510(k) Summary of Safety and Effectiveness

Date:	November 24, 2004
Submitter:	GE Medical Systems *Information Technologies* 800 Business Center Drive Mount Prospect, IL 60056
Contact Person:	Carol Alloian Sr. Regulatory Affairs Specialist GE Medical Systems, Information Technologies Phone: (847) 704-3060 Fax: (847) 704-8560
Device: Trade Name:	Centricity™ PACS System
Common/Usual Name:	Picture Archiving and Communications Systems and Workstation
Classification Names:	21 CFR 892.2050 System, Image Processing, Radiological
Predicate Device:	K023557: Centricity™ PACS Plus K033400: Seno Advantage

Device Description:

The Centricity™ PACS include the following major components: Workstation, Web Client, and Infrastructure.

The Centricity™ PACS workstation is used to view, edit, manipulate, annotate, analyze, store and distribute images and data that are stored and managed in the Centricity™ PACS infrastructure for diagnosis. This software-based product provides capabilities for the acceptance, transmission, printing, display, storage, editing and digital processing of medical images and associated data.

All acquired image data is preserved in the format in which it is received. Changes may be made to the presentation of the images. These changes are saved as display definitions only and do not alter the acquired image pixel data. Any and all display definitions applied to an image can always be reversed to the acquired state.

The Centricity™ PACS workstation may also be used in a remote location, away from the healthcare facility, as long as the workstation has the ability to connect, via network, to the primary healthcare facility where the Centricity™ PACS infrastructure is located.

The Centricity™ PACS Workstation extends its diagnostic and productivity capabilities into the mammography reading environment and may also be used for the primary interpretation of digital mammography images.

The Centricity™ PACS Workstation can also provide the hardware and OS platform for users to integrate and operate 3rd party software and/or other GE software applications such as

RIS, voice recognition, or advanced imaging analysis (for example 3D reconstruction, MIP/MPR, and bone templating, etc.) and view any data presented through those applications.

The Centricity™ PACS Workstation software application may be sold as software only for use with 'off the shelf' PC hardware technology that meets defined minimum specifications or as a turnkey solution integrated with hardware components to be configured to meet the users specific needs

The Centricity™ Web is an internal and external image and information distribution system for the clinical review of medical images and reports. The Centricity™ Web is not intended for primary diagnosis. The Centricity™ Web is available as a supplemental sub-system to Centricity™ PACS or as a stand-alone Web-based image and information distribution system.

The Centricity™ PACS Infrastructure consists of a combined set of servers and software applications, which together with the Centricity™ PACS workstation and the Centricity™ Web, make up the Centricity™ PACS.

Centricity™ Enterprise Archive delivers a complete, scalable storage solution for diagnostic images. Images can be stored in uncompressed, lossless, lossy or in Wavelet/Multi-resolution formats. The system also has the ability to send data to DICOM ready devices via the DICOM standard protocol. It is a DICOM compliant solution for image storage, retrieval and transmission. The Enterprise Archive provides redundancy in long-term storage in several ways, including Redundant Archives, Media Copy, and Application Service Provider (ASP) Archive.

Intended Use: The Centricity™ PACS provides scaleable image, data management and storage solutions for medical imaging. The system is intended for the storage, reading, diagnostic review, analysis, annotation, distribution, printing, editing, and processing of digital images and data acquired from diagnostic imaging devices such as Computed Tomography (CT), Magnetic Resonance (MR), Computed Radiography (CR), Digital X-Ray (DX), Digital Mammography (MG), Ultrasound (US), Nuclear Medicine (NM), Positron Emission Tomography (PET), X-Ray Angiography (XA), and any other DICOM devices.

The Centricity™ PACS Workstation is intended for use as a primary diagnostic and analysis tool for diagnostic images by trained healthcare professionals, including radiologists, physicians, technologists, clinicians and nurses. It is also intended for use as a clinical review workstation throughout the healthcare facility. The workstation interface provides the user with a means to display, manipulate, archive, print, and export images when connected with the Centricity™ PACS infrastructure.

To be viewed for primary interpretation, the digital mammography images must be acquired from an FDA approved Full Field Digital Mammography (FFDM) device for primary interpretation. Furthermore, the FFDM must be able to provide, to the Centricity™ PACS, a viewable DICOM 'for presentation' mammography image as approved by the FDA for primary interpretation. Images that are printed to film must be printed using a FDA approved printer for the diagnosis of digital mammography images.

To be viewed for primary diagnosis, digital mammography images must be viewed on a display system that has been cleared by the FDA for the diagnosis of digital mammography images.

The Web client software allows the user to display and manipulate images stored in the Centricity™ PACS or other DICOM archive device including the Centricity™ Enterprise Archive. The Centricity™ Web is not intended for primary diagnosis.

The Centricity™ Infrastructure provides for the system's database management, storage, printing, HL-7 interfacing, and all DICOM services such as Store, Print, Query/ Retrieve, Send, etc.

It is the user's responsibility to ensure quality, ambient light conditions and image compression ratios are consistent with the clinical application.

Technology: The Centricity™ PACS employs the same functional scientific technology as its predicate devices

Test Summary: The Centricity™ PACS System complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the Centricity™ PACS System:

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

Conclusion: The Centricity™ PACS System is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2005

GE Medical Systems
% Mr. Marc M. Mouser
Senior Project Engineer/
Program Reviewer
Conformity Assessment Services
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

Re: K043415
Trade/Device Name: Centricity™
PACS System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 4, 2005
Received: January 6, 2005

Dear Mr. Mouser:

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 (Premarket Approval), 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 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" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

K043415 filed on November 24, 2004

Device Name: Centricity™ PACS System

Indications for Use:

The Centricity™ PACS provides scaleable image, data management and storage solutions for medical imaging. The system is intended for the storage, reading, diagnostic review, analysis, annotation, distribution, printing, editing, and processing of digital images and data acquired from diagnostic imaging devices such as Computed Tomography (CT), Magnetic Resonance (MR), Computed Radiography (CR), Digital X-Ray (DX), Digital Mammography (MG), Ultrasound (US), Nuclear Medicine (NM), Positron Emission Tomography (PET), X-Ray Angiography (XA), and any other DICOM devices.

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Prescription Use ____X__ (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)

David G. Lewin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043415