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GE Medical Systems Information Technologies

K023557

Centricity PACS Plus
510 (k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)

1. **Identification of submitter:**
   Scott R. Evans
   Regulatory Affairs Specialist
   Telephone: 847-704-8878
   Fax: 847-704-8560
   Date Prepared: September 26th, 2002

2. **Identification of Product:**

Device name	Centricity PACS Plus
Classification name	PACS per 21CFR Section 892.2050
Manufacturer/ Distributor	General Electric Medical Systems 800E. Business Center Drive Mount Prospect, IL 60056 USA

3. **Marketed Devices**

   Centricity PACS Plus is substantially equivalent to the devices listed below:

Model:	Platinum Reading and Review Workstation
Manufacturer:	General Electric Medical Systems
510 (k):	K981217
Model:	Siemens SieNET
Manufacturer:	General Electric Medical Systems
510 (k):	K920319

4. **Device Description :**

   See Attachment #2

5. Indications for Use

The Centricity PACS Plus system is used to transmit, store and display images throughout a clinical environment. The Centricity PACS Plus is an image display software application that is intended for use by qualified physicians and other personnel for reading, diagnostic review, and analysis of digital images acquired from imaging devices such as CT, MR, CR, DX, MG, US, NM, PET, and other devices. As a part of the PACS Plus system the Centricity RA1000 is used to view digital images that are obtained from a GE Centricity PACS System, or another DICOM device.

6. Comparison with Predicate Device

Centricity PACS Plus is substantially equivalent to the devices listed below:

Model:	Platinum Reading and Review Workstation
Manufacturer:	General Electric Medical Systems
510 (k):	K981217

Model:	Siemens SieNET
Manufacturer:	General Electric Medical Systems
510 (k):	K920319

These workstations allow easy selection, review, processing, filming and media interchange of multi-modality images from a variety of diagnosis imaging systems.

7. Conclusions

Centricity PACS Plus brings additional features in order to integrate seamlessly into the Radiology Department Workflow.

The entire potential new hazards has been studied and controlled by a Risk Management Plan:

- Risk Management Summary
- A software development and validation process
- A software verification plan

Centricity PACS Plus provides images comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

General Electric Medical Systems
% Mr. Heinz Joerg Steneberg
Division Manager Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K023557
Trade/Device Name: Centricity PACS Plus
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 21, 2002
Received: October 23, 2002

Dear Mr. Steneberg:

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); 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.

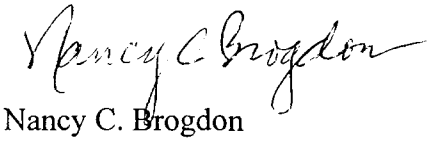
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K023557

Device name: Centricity PACS Plus

Indication For Use:

The Centricity PACS Plus system is used to transmit, store and display images throughout a clinical environment. The Centricity PACS Plus is an image display software application that is intended for reading, diagnostic review, and analysis of digital images acquired from imaging devices such as CT, MR, CR, DX, MG, US, NM, PET, and other devices. As a part of the PACS Plus system the Centricity RA1000 is used to view digital images that are obtained from a GE Centricity PACS System, or another DICOM device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023557