K042525

OCT 1 - 2004

Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date:	August 27, 2004
Submitter:	GE Medical Systems *Information Technologies* *(Formerly* APPLICARE MEDICAL IMAGING, B.V) Sparrenheuvel 38 Zeist 3708 JE Netherlands
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 Radiology RA600 / Centricity Cardiology CA1000 / Centricity Digital Hardcopy Workstation
Common/Usual Name:	Picture Archiving and Communications Systems Workstation
Classification Names:	21 CFR 892.2050 System, Image Processing, Radiological
Predicate Device:	K982862 Radworks Medical Imaging Software with Quality Control Module K023100 Accusketch Cardiac Quantitative Analysis System with Advanced Analysis Components
Device Description:	Centricity Radiology RA600 / Centricity Cardiology CA1000 / Centricity Digital Hardcopy workstation is a PC-based DICOM workstation platform which provides scaleable image and data management solutions for medical imaging. This software-based product provides capabilities for the acceptance, transmission, printing, display, storage, editing and digital processing of medical images and associated data. RA600/CA1000 / Digital Hardcopy may be combined with a PACS network or connected directly to a modality through the use of DICOM networking. The RA600/CA1000 / Digital Hardcopy software application may be sold as a standalone product for use with 'off the shelf' PC hardware that meets minimum specifications or as a turnkey solution integrated with hardware components to be configured to meet the users specific needs. RA600 / CA1000 / Digital Hardcopy can also provide the hardware and OS platform for a user to operate 3rd party software and/or other GE software applications such as RIS, voice recognition, or advanced imaging analysis, and view any data presented through those applications. RA600 / CA1000 can act as an image repository for the Centricity Web Viewer application. Targeted users of this system are trained professionals, including radiologists, cardiologists, physicians, technologists and nurses.

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Intended Use: RA600/CA1000/Digital Hardcopy is intended for viewing and diagnostic interpretation of images acquired from CT, MR, CR, DR, US, XA and other DICOM-compliant medical imaging systems when installed on suitable commercial–standard PC hardware. RA600 / CA1000 is intended for use as a primary diagnostic and analysis workstation in Radiology/ Cardiology or other departments. It is also intended for use as a clinical review workstation throughout the healthcare facility and may be part of a larger PACS configuration.

Digital Hardcopy is intended for use primarily as a workstation for the high volume burning of CDs or DVDs containing DICOM medical images and associated diagnostic report or analysis information. CD /DVD burning and disk labeling are done via a commercially available external robotics device.

RA600/CA1000/Digital Hardcopy receives imaging studies and data over LAN, WAN, intranet or internet from a PACS server or directly from a DICOM –compliant modality or archive utilizing both lossless and lossy compression. It is the user's responsibility to ensure quality, ambient light conditions and image compression ratios are consistent with the clinical application. The RA600/CA1000/Digital Hardcopy may interface with various information systems within the healthcare environment, such as the HIS, RIS, and CVIS. It may be sold as software only, or as a turnkey system.

Technology: RA600 / CA1000 / Digital Hardcopy has an application interface which allows for the exchange of patient and study information, and the execution of basic application behavior commands (e.g. open study), with GE or other third party applications. This allows RA600 / CA1000 / Digital Hardcopy to interface with other applications including, but not limited to Cardiovascular Information Systems (CVIS), Radiology Information Systems (RIS), Clinical Information Systems, and other clinical software packages such as Orthopedic Templating and surgery planning software.

The RA600/CA1000/Digital Hardcopy software application may be sold as a standalone product for use with 'off the shelf' PC hardware that meets minimum specifications or as a turnkey solution integrated with hardware components to be configured to meet the users specific needs. The RA600 / CA1000 / Digital Hardcopy Turnkey Workstation consists of a PC computing tower, software, high-resolution grayscale and/or color monitor(s), a keyboard and a mouse or other hand-based human interface device. The RA600 / CA1000 workstation can optionally include external or internal CD, DVD, or MOD drives for reading or writing to the respective media. The Centricity Digital Hardcopy Workstation uses a commercially available robotics system for automated CD or DVD publishing and disk labeling.

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Test Summary: The RA600 / CA1000 / Digital Hardcopy 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 RA600 / CA1000 / Digital Hardcopy:

- 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 Radiology RA600 / Centricity Cardiology CA1000 / Centricity Digital Hardcopy Workstation is as safe, as effective, and performs as well as the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 - 2004

GE Medical Systems
Information Technologies
% Ms. Chantel Carson
CAS Manager
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K042525
Trade/Device Name: Centricity Radiology RA600/Centrici
Cardiology CA1000/ Centricity Digital Hardcopy
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 15, 2004
Received: September 17, 2004

Dear Mr. Carson:

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

K042525

510(k) Number (if known): Unknown; 510(k) filed on August 27, 2004

Device Name: Centricity Radiology RA600/ Centricity Cardiology CA1000/ Centricity Digital Hardcopy

Indications for Use:

RA600/CA1000/Digital Hardcopy is intended for viewing and diagnostic interpretation of images acquired from CT, MR, CR, DR, US, XA and other DICOM-compliant medical imaging systems when installed on suitable commercial–standard PC hardware. RA600 / CA1000 is intended for use as a primary diagnostic and analysis workstation in Radiology/ Cardiology or other departments. It is also intended for use as a clinical review workstation throughout the healthcare facility and may be part of a larger PACS configuration.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__X___ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042525

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