



K 112 570

NOV 3 0 2011

GE Healthcare
510(k) Premarket Notification Submission
Section 5: 510(k) Summary

510(k) Summary

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

Date: August 31, 2011

Submitter: GE Healthcare
540 West Northwest Highway
Barrington, IL 60010

Primary Contact Person: John Manarik
Regulatory Affairs Manager
GE Healthcare
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Secondary Contact Person: Jeme Wallace
Regulatory Affairs Director
GE Healthcare
Phone: 847-277-4468
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Device: Trade Name: Centricity* Cardio Imaging

Common/Usual Name: Picture Archiving and Communication System

Classification Names: 21 CFR 892.2050, System, Image Processing,
Radiological

Product Code: LLZ

Predicate Device(s): GE Healthcare's Centricity* PACS-IW and TomTec
Imaging System's Image Arena



Device Description: Centricity* Cardio Imaging is a web enabled cardiology Picture Archiving and Communication System that offers highly integrated imaging, workflow and information management in a single platform. Centricity* Cardio Imaging leverages a rich ECHO/NIPV clinical toolset and the data management capability from its predicate devices.

Centricity* Cardio Imaging is a software only medical device comprised of a client and server. The client is web-accessed and provides the user-facing functions such as the work list, viewing, and reporting. The server provides background functions such as data storage, data transfer, database management, application deployment, user authentication, user profiles, licensing, and hanging protocols.

Centricity* Cardio Imaging is a software only medical device intended for use with commercially available off the shelf hardware.

Intended Use: Centricity* Cardio Imaging is a software only Picture Archiving and Communication System (PACS). It will be sold as a software only device to operate on general purpose computing hardware. Centricity* Cardio Imaging receives medical images and other information from various data sources. Information can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

Centricity* Cardio Imaging is intended to assist trained professionals in the viewing, analysis, and diagnostic interpretation of images and other information for the diagnosis and treatment of cardiac and vascular disease. These trained professionals include but are not limited to physicians, cardiologists, radiologists, nurses, medical technicians, and assistants.



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Centricity* Cardio Imaging is not intended for use in the patient vicinity.

Technology: Centricity* Cardio Imaging employs the same fundamental scientific technology as its predicate devices, Centricity* PACS IW and Tomtec Imaging Systems Image Arena.

Centricity* Cardio Imaging receives medical images and other information from various data sources, and provides the capability to analyze echocardiography and NIPV images the same as its predicate devices.

Information can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations the same as its predicate devices.



Determination of Substantial Equivalence: Summary of Non-Clinical Tests

Centricity* Cardio Imaging and its applications comply 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
- Testing on unit level (Verification)
- Integration testing (Verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket notification submission, Centricity* Cardio Imaging, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Centricity* Cardio Imaging product to be as safe, as effective and substantially equivalent in performance to its predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. John Manarik
Regulatory Affairs Manager
GE Healthcare
HCIT
540 West Northwest Highway
BARRINGTON IL 60010

NOV 30 2011

Re: K112570
Trade/Device Name: Centricity Cardio Imaging
Regulation Number: 21 CFR 872.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 31, 2011
Received: September 6, 2011

Dear Mr. Manarik:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

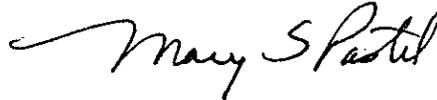
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety 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,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Centricity Cardio Imaging

Indications for Use: K112570

Centricity* Cardio Imaging is a software only Picture Archiving and Communication System (PACS). It will be sold as a software only device to operate on general purpose computing hardware. Centricity* Cardio Imaging receives medical images and other information from various data sources. Information can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

Centricity* Cardio Imaging is intended to assist trained professionals in the viewing, analysis, and diagnostic interpretation of images and other information. These trained professionals include but are not limited to physicians, cardiologists, radiologists, nurses, medical technicians, and assistants.

Prescription Use Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No
(Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K 112570