K073138

510(K) Summary
As Required by 21 CFR 807.92

510(k) Number: _____

FEB 26 2008

1. Submitter Information

Submitter Name: GE Medical Systems SCS
283, rue de la Minière
78533 Buc Cedex, FRANCE

Establishment Reg: 9611343

Contact Person: Stephen Slavens
Global RA Premarket Director
3000 N Grandview Blvd.
Waukesha, WI 53188
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stephen.slavens@ge.com

Date Prepared: February 21, 2008

2. Device information

Trade Name: CardIQ Xpress 2.0
Common Name: Computed Tomography X-Ray System
Classification Name: System, x-ray, tomography, computed
Procode: JAK
Class: Class II per 21 CFR 892.1750

3. Predicate Devices

CardIQ Xpress 2.0 is substantially equivalent to the predicate device listed below:

Device Name	FDA Clearance
GE CardIQ Analysis III	K041267

4. Device Description

The GE Medical Systems CardIQ Xpress 2.0 software is a post processing software option for the Advantage Workstation (AW) Platform, CT scanner, PACS or Centricity systems. This product can be used in the analysis of CT angiographic images to view the coronary vessels to determine if the patient has normal coronary arteries, arteriolosclerosis or severe stenosis, which needs to go on for treatment. This software also can look at the heart structures to include valve imaging, heart motion and ejection fraction. CardIQ Xpress 2.0 contains both graphic and text report capabilities with predefined templates for ease of use.

5. Indication for Use

CardIQ Xpress 2.0 is intended to provide an optimized non-invasive application to analyze cardiovascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

CardIQ Xpress 2.0 is a CT, non-invasive, image analysis software package, which aids in diagnosing of cardiovascular disease to include, coronary artery disease, functional parameters of the heart, heart structures and follow-up for stent placement, bypasses and plaque imaging. **CardIQ Xpress 2.0** offers unique tools such as automatic tracking, which will pre-process the CT data into multiple viewing ports to allow for an expedited read time improving workflow. With **CardIQ Xpress 2.0** the user can color code the myocardial tissue to show hypo/hyper-dense areas in the myocardial tissue of the heart. With the IVUS-like view the user can color code the HU units of the plaque to better visualize the difference between calcified and non-calcified plaque in the wall of the vessel and the lumen to determine the amount of atherosclerosis. The user can see the different valve planes along with a variety of new layouts to align the heart. The IVUS-like view is created by applying GE's Volume Rendering on a cross-section perpendicular to the detected centerline. This view merely displays a cross section as in IVUS imaging and color codes like IVUS images. No new or additional diagnostic information is added.

CardIQ Xpress 2.0 is for use on the Advantage Workstation (AW) platform, CT Scanner, PAC or Centricity stations, which can be used in the analysis of 2D or 3D CT angiography images/data derived from DICOM 3.0 CT scans.

6. Summary of non-clinical and/or clinical tests and results

The software was designed to meet the following standards:

Standard	Standards Organization	Standard Title
PS 3.1 - 3.18	NEMA	Digital Imaging and Communications in Medicine (DICOM)
SW68	AAMI/ANSI	Medical Device Software - Software life cycle processes

Software and medical device design validation have been completed. Medical device design included testing on phantoms and evaluation of previously acquired diagnostic images.

The results concluded the device was acceptable for use.

7. Statement of Equivalence

The General Electric CardIQ Xpress 2.0 workstation software is equivalent to the predicate General Electric CardIQ Analysis III device and is safe and effective for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

FEB 26 2008

GE Medical Systems
% Mr. Jay Y. Kogoma
Sr. Staff Engineer – Medical Devices
Intertek Testing Services NA, Inc.
2307 E. Aurora Road, Unit B7
TWINSBURG OH 44087

Re: K073138
Trade/Device Name: CardIQ Epress 2.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 8, 2008
Received: February 11, 2008

Dear Mr. Kogoma:

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 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): K073138

Device Name: **CardIQ Xpress 2.0**

Indications For Use:
CardIQ Xpress 2.0 is intended to provide an optimized non-invasive application to analyze cardiovascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073138