K041267

MAY 27 2004



# 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).

**Submitter** Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
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GE Medical Systems W-400
3000 North Grandview Blvd.
Waukesha, WI 53188 USA
Date Prepared: February 13, 2004.

## PRODUCT IDENTIFICATION

Name: CardIQ Analysis III

Classification Name: Accessory to Computed Tomography System

Manufacturer : General Electric Medical Systems
283, rue de la Minière
78533 Buc Cedex, FRANCE

Distributor: General Electric Medical Systems, Buc, France.

**Marketed Devices** The CardIQ Analysis III is substantially equivalent to the devices listed below:

| | |
|---|---|
| Model: | CardIQ Analysis II |
| Manufacturer: | General Electric Medical Systems, Buc, France |
| 510(k) #: | K020796 |
| Model: | CardIQ Function |
| Manufacturer: | General Electric 3200 N. Grandview Blvd. Waukesha, WI 53188 |
| 510(k) #: | K013422 |

**Device Description:**

CardIQ Analysis III is a post processing software option that can be used in the analysis of CT angiographic images to display structures of the heart in a MIP, reformat or volume rendering view. When the heart is displayed the software has the ability to measure the diameter of the vessel or hounsfield units within a coronary arteries to determine the size of a vessel or plaque density within a vessel. Functional parameters of the heart can also be determined when images of end systole and end diastole are present. Diameters, densities, functional parameters and images can all be printed to reports or saved to the AW workstation. It is a software option for the GE family of LightSpeed multi-slice CT scanners.

**Indications for Use:**

CardIQ Analysis III is a CT image analysis software package, which allows the visualization of 2D and 3D medical image data of the heart derived from DICOM 3.0 compliant CT scans for the purpose of cardiovascular disease assessment. It provides functionally for 2D/3D rendering, assessment of calcified and non-calcified plaque to determine the densities of the plaque within a coronary artery, ventricular function of the heart, and measurement tools to detect coronary artery stenosis. This product can be used to aid a trained physician for to process, render, review, archive, print and visualizing cardiac anatomy and coronary vessels. CardIQ Analysis III will run on the AW workstation, scanner operator console and PACS system.

**Comparison with Predicate:**
The functional features of the CardIQ Analysis III software package are substantially equivalent to that of the following device:

| Device Name | FDA Clearance Number |
|---|---|
| CardIQ Analysis II | K020796 |
| CardIQ Function | K013422 |

**Adverse Effects on Health:**

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

**Conclusions:**

The CardIQ Analysis III does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the CardIQ Analysis III to be equivalent to those of CardIQ Analysis II (K020796) and CardIQ Function (K013422).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2004

Mr. Tamas Borsai
Program Manager 510(k) Review
TUV Rheinland of North America, Inc.
Medical Division, Newton Office
12 Commerce Road
NEWTON CT 06470

Re: K041267
Trade/Device Name: CardIQ Analysis III
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: May 3, 2004
Received: May 12, 2004

Dear Mr. Borsai:

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041267

*General Electric Medical Systems*

## STATEMENT OF INTENDED USE

**Device name:** CardIQ Analysis III

**Intended Use:**

CardIQ Analysis III is a CT image analysis software package, which allows the visualization of 2D and 3D medical image data of the heart derived from DICOM 3.0 compliant CT scans for the purpose of cardiovascular disease assessment. It provides functionally for 2D/3D rendering, assessment of calcified and non-calcified plaque to determine the densities of the plaque within a coronary artery, ventricular function of the heart, and measurement tools to detect coronary artery stenosis. This product can be used to aid a trained physician for to process, render, review, archive, print and visualizing cardiac anatomy and coronary vessels. CardIQ Analysis III will run on the AW workstation, scanner operator console and PACS system.

(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 K041267