MAY 3 0 2006

K061370
Page 1 of 3

GE Healthcare

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
Tel: (262) 544-3894
Fax: (262) 544-3202
GE Healthcare W-440
3000 North Grandview Blvd.
Waukesha, WI 53188 USA
Date Prepared: April 19, 2006

PRODUCT IDENTIFICATION

Name: CardIQ Fusion
Classification Name: Accessory to Computed Tomography System per 21 CFR 892-1750
Manufacturer: GE Medical Systems SCS
283, rue de la Minière
78533 Buc Cedex, FRANCE

Distributor: GE Healthcare, P.O. Box 414, Milwaukee, WI 53210

Marketed Devices CardIQ Fusion is substantially equivalent to the devices listed below:

- Model: CardIQ Pro, 510(k) #K041267
- Manufacturer: GE Medical Systems SCS, Buc, France
- Model: CT/PET Fusion, 510(k) # K010336
- Manufacturer: GE Medical Systems SCS, Buc, France
- Model: CardIQ Function, 510(k) # K013422
- Manufacturer: GE Healthcare, 3200 North Grandview Blvd, Waukesha, WI 53188 USA
- Model: ECToolbox with HeartFusion, 510(k) # K040141
- Manufacturer: Syntermed, INC, USA
- Model: Advanced Vessel Analysis II, 510(k) # K060779
- Manufacturer: GE Medical Systems SCS, Buc, France

Device Description:

CardIQ Fusion is a post processing analysis software package designed to assist Radiologists, Nuclear Medicine Doctors, Cardiologists, and other clinicians in the evaluation and assessment of heart including its coronary vasculature and perfusion conditions.

CardIQ Fusion is a software post-processing package for the Advantage Workstation (AW) platform, PET/CT and CT scanners and PACS reading stations. It is an additional tool for the

K061370
Page 2 of 3

analysis of 3D CT angiographic cardiac images/data providing a number of display, measurements and batch filming/archive features to study user-selected vessels. Also included is the capability to visualize reformatted CT/PET/SPECT perfusion and viability data. Finally, it provides different ways of visualizing CT anatomy fused with PET/SPECT functional information.

Indications for Use:

CardIQ Fusion is intended to provide an optimized non-invasive application to analyze vascular anatomy and pathology, aid in the assessment of functional data e.g. PET perfusion, and aid in tailoring treatment plans based on the fused anatomical and functional information. Anatomical data could be from a set of Computed Tomography (CT) Angiographic images while functional data could be from PET, SPECT, or processed CT data.

CardIQ Fusion is a software post-processing package for the Advantage Workstation (AW) platform, PET/CT and CT scanners and PACS reading stations. It is an additional tool for the analysis of 3D CT angiographic cardiac images/data providing a number of display, measurements and batch filming/archive features to study user-selected vessels. Also included is the capability to visualize reformatted CT/PET/SPECT perfusion and viability data. Finally, it provides different ways of visualizing CT anatomy fused with PET/SPECT functional information.

With CardIQ Fusion, clinicians have the opportunity to overlay functional information over the (CT) anatomy of a patient's heart, and thus, they can potentially tailor their decision for that particular patient. CardIQ Fusion provides the visualization of the vessels in several different formats including 3D rendering, curved reformats. Once vessels are visualized, tools are available for sizing the vessel, analyzing calcified and non-calcified plaque to determine the densities of plaque within a vessel, measure areas of abnormalities within a vessel (like stenosis, plaque).

Functional data could come from PET, SPECT, or processed CT data for perfusion information. The functional and anatomical data could come from the same scanner as in the case of PET/CT scanner; or they could come from separate scanners like stand alone NUC camera and stand alone CT scanner.

Comparison with Predicate:

CardIQ Fusion is substantially equivalent to the predicate devices listed below:

Device Name	FDA Clearance Number
CardIQ Pro	K041267
CT PET Fusion	K010336
CardIQ Function	K013422
AVA II	K060779
ECToolbox with HeartFusion	K040141

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:

CardIQ Fusion 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 Fusion to be equivalent to those of CardIQ Pro, CT PET Fusion, ECToolbox with HeartFusion, CardIQ Function, and Advanced Vessel Analysis II.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 30 2006

GE Healthcare
% Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd, Unit B7
TWINSBURG OH 44087

Re: K061370
Trade/Device Name: CardIQ Fusion
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 16, 2006
Received: May 17, 2006

Dear Mr. Devine:

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/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): K061370

Device Name: CardIQ Fusion

Indications for Use:

CardIQ Fusion is intended to provide an optimized non-invasive application to analyze vascular anatomy and pathology, aid in the assessment of functional data e.g. PET perfusion, and aid in tailoring treatment plans based on the fused anatomical and functional information. Anatomical data could be from a set of Computed Tomography (CT) Angiographic images while functional data could be from PET, SPECT, or processed CT data.

CardIQ Fusion is a software post-processing package for the Advantage Workstation (AW) platform, PET/CT and CT scanners and PACS reading stations. It is an additional tool for the analysis of 3D CT angiographic cardiac images/data providing a number of display, measurements and batch filming/archive features to study user-selected vessels. Also included is the capability to visualize reformatted CT/PET/SPECT perfusion and viability data. Finally, it provides different ways of visualizing CT anatomy fused with PET/SPECT functional information.

With CardIQ Fusion, clinicians have the opportunity to overlay functional information over the (CT) anatomy of a patient's heart, and thus, they can potentially tailor their decision for that particular patient. CardIQ Fusion provides the visualization of the vessels in several different formats including 3D rendering, curved reformats. Once vessels are visualized, tools are available for sizing the vessel, analyzing calcified and non-calcified plaque to determine the densities of plaque within a vessel, measure areas of abnormalities within a vessel (like stenosis, plaque).

Functional data could come from PET, SPECT, or processed CT data for perfusion information. The functional and anatomical data could come from the same scanner as in the case of PET/CT scanner; or they could come from separate scanners like stand alone NUC camera and stand alone CT scanner.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061370