K061587

JUN 23 2006

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).

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Date Prepared: November 18, 2005.

PRODUCT IDENTIFICATION

Name: FullCard Analysis

Classification Name: Emission computed tomography system per 21 CFR 892- 1200

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

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

Marketed Devices FullCard Analysis is substantially equivalent to the devices listed below:

- Model: ECToolbox with HeartFusion; K040141
- Manufacturer: General Electric Medical Systems, Buc, France
- Model: Xeleris 2 Processing and Review Workstation; K051673
- Manufacturer: General Electric Medical Systems, Haifa, Israel
- Model: Advantage Workstation 4.3; K052995
- Manufacturer: General Electric Medical Systems, Buc, France
- Model: Positron mPower; K022001
- Manufacturer: Positron Corporation, Houston, TX, USA
-

Device Description:

FullCard Analysis (FCA) is a post processing analysis software package designed to assist Radiologists, Nuclear Medicine Doctors, Cardiologists, and other clinicians by offering a totally integrated package including automated processing, visualization, quantification of parameters of myocardial perfusion and function, along with simple reporting capabilities. The parameters include

perfusion, end-diastolic & end-systolic volumes, stroke volume, ejection fraction, myocardial mass, and transient ischemic dilatation.

FCA accepts Gated PET images in either transaxial or short axis orientations. The package processes images automatically but it allows the users to intervene and modify results when needed. FCA is a software post-processing package for the Advantage Workstation (AW) platform and PET/CT scanners.

Indications for Use:

FCA is an aiding tool for the clinicians to perform analysis of sets of stationary, dynamic, or gated PET transaxial images via a number of display, measurement and batch filming/archive features. The measurements include perfusion, end-diastolic & end-systolic volumes, stroke volume, ejection fraction, myocardial mass, and transient ischemic dilatation. Also included is to enable clinicians to visualize reformatted PET perfusion and viability data, make a comparison between the two. The perfusion or viability data could have been acquired under stress or rest conditions and they can be processed individually or simultaneously.

FCA allows users to customize their screens. Also, the users can export a selected set of short axis images in DICOM compliant format. These images can then be processed by an external software package to perform regional quantitative analysis, absolute and relative ratio maps of each region of the heart and topographic maps. Finally, it aids clinicians to capture the summary of quantitative and qualitative results from the study in a single summary page.

The physiological and functional data could come from the same scanner as in the case of PET/CT scanner; or they could come from separate scanners.

In summary, FCA is intended to aid clinicians in the assessment of physiological data and in refining their clinical decisions based on the quantitative and qualitative assessment of stationary, dynamic, and gated PET images.

Comparison with Predicate:

FullCard Analysis is substantially equivalent to the predicate devices listed above :

Device Name	**FDA Clearance Number**
ECToolbox with HeartFusion	K040141
Xeleris 2 Processing and Review Workstation	K051673
Advantage Workstation 4.3	K052995
Positron mPower	K022001

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:

FullCard Analysis does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of FCA to be equivalent to those of ECToolbox with HeartFusion and Xeleris 2 Processing and Review Workstation, Advantage Workstation 4.3, and Positron mPower.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 23 2006

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

Re: K061587
Trade/Device Name: Fullcard Analysis
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: June 6, 2006
Received: June 8, 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 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

GE Healthcare

Indications for Use

510(k) Number (if known): K061587

Device Name: Fullcard Analysis

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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 G. Hoganson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061587