K050559

Technologies

MAR 17 2005

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: GE Discovery VCT System

Date prepared: February 1, 2005

Establishment Name and Registration Number of Submitter

Name: GE Healthcare Technologies
(Formerly GE Medical Systems)

Registration Number: 2126677

Corresponding Official:
Larry Kroger
GE Healthcare Technologies
P.O. Box 414
Milwaukee, WI 53201
Phone: 262-544-3894
FAX: 262-548-4768

Device Classification

Classification Code: 90 KPS/90 JAK

Panel Identification: Radiology

Classification Name: Emission Computed Tomography System/ Computed Tomography System (Per 21CFR 892.1200 and 21CFR 892.1750)

Common Name: PET/CT Imaging System

Classification Class: Class II Product

Reason for 510(k) Submission

Modification of a legally marketed device.

Identification of Legally Marketed Equivalent Devices

GE Discovery ST System	K041543
GE Discovery ST System with Alternate Detector Option	K042257

Device Description

The Discovery VCT is an integrated multi-slice Computed Tomography and Positron Emission Tomography scanner. It uses CT images to correct for non-uniform attenuation of the PET images and it uses integrated CT and PET images to localize emission activity in the patient anatomy. Discovery VCT has capabilities for imaging all available PET tracers and CT contrast agents and can provide inherently registered anatomical and functional information via an integrated graphical user interface. Discovery VCT can also be used as a stand-alone head and whole body multislice CT diagnostic imaging system.

Description of Change or Modification

The Discovery VCT PET/CT System is the same as the Discovery ST system described in 510(k)s K041543 and K042257 except that the PET system is integrated with a different CT system, the GE LightSpeed VCT system.

Indications for Use of Device

The GE Discovery VCT System is intended for head and whole body attenuation corrected Positron Emission Tomography (PET) imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images.

The Discovery VCT is to be used by trained health care professionals for imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions. This can assist in the evaluation, diagnosis, staging, restaging, and follow up of lesions, disease and organ function such as (but not limited to) cancer, cardiovascular disease, and brain dysfunction. This device can also assist in radiotherapy planning.

The Discovery VCT can also be used as a stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging system.

Conclusion

In the opinion of General Electric Medical Systems, the Discovery VCT System is substantially the same in design, materials, energy sources, and technology, and is therefore substantially equivalent in terms of safety and effectiveness to the currently marketed Discovery ST System.

General Electric Company
P.O. Box 414
Milwaukee, WI 53201

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2005

GE Healthcare Technologies
% Mr. Tamas Borsai
Medical Division Manager,
Third Party Review Program
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K050559
Trade/Device Name: GE Discovery VCT System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: KPS and JAK
Dated: March 3, 2005
Received: March 3, 2005

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 (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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K050559

Device Name: GE Discovery VCT System

Indications for Use

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The Discovery VCT can also be used as a stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging 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 K050559