K042257

SEP - 8 2004

Attachment B:

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

GE Healthcare

Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact Person: D. Duersteler
Safety and Regulatory Engineering
Telephone: 262-312-7029; Fax: 262-312-7144

Date Prepared: August 18, 2004

Device Name: Discovery ST PET/CT Imaging System an with alternate detector option.
Emission Computed Tomography System, 21 CFR 892.1200, 90-KPS

Marketed Device: GE Medical Systems GE Discovery ST Positron Emission Tomography System, 510(k) Number K010641, currently in commercial distribution.

Device Description: The Discovery ST PET/CT Imaging System an with alternate detector option integrates a GE Positron Emission Tomography system and a GE LightSpeed CT System. In addition to providing CT and PET stand-alone capabilities, it uses the CT images to correct for non-uniform attenuation of the PET images and to facilitate localization of the emission activity in the patient anatomy.

Indications for Use: The GE Discovery ST System with the alternate detector option 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 ST with alternate detector option 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 ST with alternate detector option can also be used as a stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging system.

Comparison with Predicate Device: The Discovery ST with alternate detector option is of a comparable type and substantially equivalent to the currently marketed GE Discovery ST PET/CT System. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same basic design, construction, and materials, and has the same intended uses as the predicate device.

Summary of Studies: The device has been evaluated for electrical, mechanical, and radiation safety, and conforms with applicable medical device safety standards.

Clinical Tests: None required.

Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. Intended uses and fundamental scientific technology are the same as the legally marketed GE Discovery ST System. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with factory surveillance. Therefore, it is the opinion of GE Medical Systems that the Discovery ST with alternate detector option PET/CT Imaging System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Mr. D. Duersteler
Safety and Regulatory Engineering
General Electric Company
GE Medical Systems W-1250
P.O. Box 414
MILWAUKEE WI 53201

Re: K042257
Trade/Device Name: Discovery ST PET/CT Imaging System with Alternate Detector Option
Regulation Number: 21 CFR 882.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 KPS and JAK
Dated: August 18, 2004
Received: August 20, 2004

Dear Mr. Duersteler:

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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K042257

Device Name: Discovery ST PET/CT Imaging System with alternate detector option

Indications for Use

The GE Discovery ST System with the alternate detector option 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 ST with alternate detector option 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 ST with alternate detector option 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 ✓
(Per 21 CFR 801-109)

OR Over-The-Counter Use _____

David R. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042257