K012725

SEP 1 8 2001

Attachment B
Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c).

GE Medical Systems

General Electric Company
8380 Darrow Road, Twinsburg, OH 44087

Submitter: GE Medical Systems - SMV
8380 Darrow Road
Twinsburg, OH 44087

Contact Person: Geoff Cochrane
Manager, Engineering
Telephone: 330-487-6638; Fax: 330-405-7684

Date Prepared: 09-Aug-2001

Device Name: Positrace / Discovery VI Dual Mode PET/CT Oncology System
Emission Computed Tomography System, 21 CFR 892.1200, 90-KPS

Marketed Device: Positrace Dual Mode PET/CT Oncology System, 510(k) Number K001681, currently in commercial distribution.

Device Description: The Positrace / Discovery VI PET/CT scanner is a whole-body scanner primarily intended for oncology applications. It consists of a patient table, PET scanner, CT scanner, UNIX workstation, monitor, keyboard, mouse, modem, and network interface.

Indications for Use: Combination of whole-body positron emission tomography (PET) scanning with a diagnostic quality computed tomography scanner. Intended for use as a diagnostic imaging device.

Comparison with Predicate Device: The Positrace / Discovery VI is of a comparable type and substantially equivalent to the currently marketed Positrace scanner. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same basic design, 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 Positrace scanner. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and EN 46001 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 Positrace / Discovery VI scanner 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 1 8 2001

Mr. Geoffrey Cochrane
Engineering Manager
GE Medical Systems
General Electric Company
8380 Darrow Road
TWINSBURG OH 44087

Re: K012775
Trade/Device Name: GE Positrace/Discovery VI
PET/CT Dual Mode Oncology Scanner
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Product Code: 90 KPS
Regulation Number: 21CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Product Code: 90 JAK
Regulatory Class: II
Dated: August 9, 2001
Received: August 20, 2001

Dear Mr. Cochrane:

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 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.

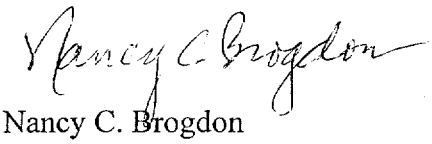
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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:

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" (21 CFR Part 807.97). 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K012775

Device Name: **Discovery VI Dual Mode PET / CT Oncology System**

Indications for Use

Combination of whole-body positron emission tomography (PET) scanning with a diagnostic quality computed tomography scanner. Intended for use as a diagnostic imaging device. Used with appropriate radiopharmaceuticals, it produces images which depict the anatomical distribution of radioisotopes within the human body. The integrated CT system is intended to provide an enhancement to the emission images by compensating for the attenuation effects of the human body. It will also provide registration of anatomical and physiological images to localize the radioisotope activity in the patient anatomy. The CT or PET scanner may be used independently.

(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 K012775