JUN - 7 2004

510(k) SUMMARY

[As required by 21 CFR 807.87(h)]

K040933

Identification of Submitter

Submitter: Alaine Medio, RAC
Senior Regulatory Affairs Specialist
CTI PET Systems, Inc.
810 Innovation Drive
Knoxville, TN 37932

Telephone No: (865) 218-2703
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Date of preparation: May 7, 2004

Identification of the Product

Device Proprietary Name: ECAT HRRT
Common Name: Positron Emission Tomography (PET) Scanner
Classification Name: Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
ECAT ACCEL	CTI PET Systems (CPS)	K962797
E.CAM LSO 311	CTI PET Systems (CPS)	K981027

Device Description

The CTI PET Systems ECAT HRRT is a new positron emission tomography (PET) scanner system. The ECAT HRRT PET scanners utilize flat panel detector heads, combined LSO (Lutetium Oxyortho-Silicate) / LYSO (Lutetium Yttrium Oxyortho-Silicate) crystal detector technology. The HRRT consists of eight detector panels in an octagonal arrangement completely encircling the bore of the Gantry.

A Patient Handling System (PHS) will be offered as an optional accessory with the scanner. This PHS is similar to other PHS systems currently marketed with the exception that it has been specifically designed for use with the HRRT. Modifications have been made to accommodate the different size gantry bore and shorter horizontal travel associated with this gantry.

The acquisition computer system is comprised of an Intel based acquisition PC, a Raid system disk and a console connected via fibre channel to the HRRT electronics. This is the same as is used in the ECAT ACCEL (K002584) with the exception of the RAID disk.

Software is based on the Standard ECAT software (7.x), which is used with the ECAT ACCEL system. Modifications have been made to accommodate the new acquisition system, enlarged data sets (due to increased resolution) and user interface to allow clinician flexibility in reconstruction.

Indications for Use

The CTI PET Systems Inc. ECAT HRRT positron emission tomography (PET) scanners are intended to be utilized by appropriately trained health care professionals to image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic and physiologic functions within the human body.

Comparison with Predicate Devices

The ECAT HRRT PET scanner leverages much of the already proven technology, as well as many components and features of currently produced CPS PET tomographic systems. The 360 degree field of view (FOV) detector geometry surrounding the patient port is similar to that of the CPS ECAT ACCEL PET scanner (K002584). The flat panel detectors, LSO/LYSO combined crystal detector technology, and coincidence point source transmission scanning design concepts were borrowed from the E.CAM LSO 311 PET/SPECT system (K981027). The patient handling system (PHS) offered as an option with ECAT HRRT scanner is similar to the PHS used on the CPS ECAT ACCEL. The Advanced Computational System (ACS), used to store and process acquired PET data into sinograms, as well as the reconstruction computer, control console, and the ECAT software are updated versions of those components used in the ECAT ACCEL scanner.

Safety and Effectiveness

The CPS ECAT HRRT system has been designed to comply with applicable industry safety standards for this type of medical equipment including the international standard IEC 60601-1, General Requirements for the Safety Electrical Medical Equipment. Performance of the ECAT HRRT system has been tested by CPS and found to meet its predetermined PET performance specifications.

Substantial Equivalence Determination

In the opinion of CPS, the ECAT HRRT PET scanner utilizes the same scientific technology as the predicate ECAT ACCEL and E.CAM LSO 311 PET/SPECT systems and raises no new questions with regard to its safety and effectiveness. Therefore, we believe the ECAT HRRT is substantially equivalent to those tomographic systems with respect to design, material and composition, energy source, and radiation safety characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2004

Ms. M. Alaine Medio, RAC
Senior Regulatory Affairs Specialist
CTI PET Systems, Inc.
CPS Innovations
810 Innovation Drive
KNOXVILLE TN 37932

Re: K040933
Trade/Device Name: ECAT HRRT PET Scanner
Regulatory Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: April 8, 2004
Received: April 9, 2004

Dear Ms. Medio:

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

510(k) Number (if known): K040933

Device Name: ECAT HRRT PET Scanner

Indications for Use:

CPS ECAT positron emission tomography (PET) scanners are intended to be utilized by appropriately trained health care professionals to image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic and physiologic functions within the human body.

(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)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040933