NOV 8 2002

K023518

510(k) SUMMARY

[As required by 21 CFR 807.87(h)]

Identification of Submitter

Submitter:	CTI PET Systems, Inc. 810 Innovation Drive Knoxville, TN 37932
Contact Person:	William Skremsky Senior Regulatory Affairs Specialist
Telephone No:	(865) 218-2522
Fax No:	(865) 218-3000
Date of preparation:	October 18, 2002

Identification of the Product

Device Proprietary Name:	ECAT LSO PET/CT 16
Common Name:	Combination Positron Emission Tomography (PET) and X-Ray Computed Tomography (CT)
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
ECAT LSO PET/CT	CTI PET Systems (CPS)	K013504

Device Description and Comparison to the Unmodified Device

The ECAT LSO PET/CT 16 is a combined positron emission tomography (PET) and X-ray computed tomography (CT) scanner. This dual modality tomograph is a modified version of the ECAT LSO PET/CT (K013504) and will utilize the same PET component as the ECAT LSO PET/CT scanner. However, in place of the Siemens P10 SOMATOM EMOTION CT component that uses a single or dual row of X-Ray detectors, the ECAT LSO PET/CT 16 will be configured with the Siemens P30 SOMATOM SENSATION CT, utilizing 24 rows of X-Ray detectors and having the capability to acquire 16 slices of X-Ray data simultaneously. As with the unmodified system, 2D PET acquisition septa and the PET transmission sources are not incorporated in the modified ECAT LSO PET/CT. PET emission data is acquired only in 3D mode and PET attenuation correction map data are obtained from the CT. The PET and CT components are contained within a unified housing similar to the original ECAT LSO PET/CT to create an integrated, PET, CT, and combined PET/CT, tomographic imaging system.

The ECAT LSO PET/CT 16 gantry structure, patient handling system (PHS), advanced computational system (ACS 3), workstation and software will be similar to the ECAT LSO PET/CT with only minor modifications. The gantry's unified housing has been modified cosmetically and enlarged to accommodate the increased size of the SOMATOM P30 CT gantry. In addition, the patient handling system (PHS) has been modified to ensure adequate

dual scan coverage for PET and CT patient scanning, with the increased axial depth of the new SOMATOM P30 CT gantry. The high performance Siemens P30 SOMATOM SENSATION CT with 16 slice capability provides for faster and higher quality CT acquisitions but does not otherwise affect performance of the ECAT LSO PET/CT 16.

The ECAT LSO PET/CT 16 scanner is intended for use primarily as a clinical, whole-body oncology machine with high-end spiral CT performance and fast patient-throughput clinical PET performance. As on the original system, the CT component will also enhance PET scans by allowing fast, essentially noise-free, attenuation correction for PET studies and by providing precise anatomical reference through fused PET and CT images. In addition, the ECAT LSO PET/CT 16 will retain mechanical isolation and independent functionality of the PET and CT scanning systems, thereby allowing for most standard CT and PET clinical diagnostic protocols to be available on the PET/CT system.

The purpose of introducing this modified ECAT LSO PET/CT 16 system is to offer a combined PET and CT tomograph having very high CT performance with the fast throughput of the ECAT ACCEL PET, as a higher performance alternative to the presently distributed ECAT LSO PET/CT system.

Intended Use

The CPS ECAT LSO PET/CT 16 system is a combined positron emission tomography (PET) and X-ray computed tomography (CT) scanner. This PET/CT scanner is intended to be utilized by appropriately trained health care professionals to 1) image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body; and 2) to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

The PET and the CT functions of this system can also be used in combination to provide high resolution, noise free CT attenuation correction maps for PET images and, additionally, utilized to produce fused CT and PET images, providing detailed anatomic and metabolic function information in a single image.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube and the simultaneous translation of the patient.)

Safety and Effectiveness

The CPS ECAT LSO PET/CT 16 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 and UL 187, the X-Ray Equipment Standard for Safety. The CT component has been tested and meets the requirements of the applicable US Federal Performance Standards and regulations of 21CFR 1020.30 and 1020.33. The PET component is unmodified from the previously cleared ECAT LSO PET/CT (K013504). The combined PET/CT system has been tested by CPS and found to meet its predetermined performance requirements.

Substantial Equivalence Determination

In the opinion of CPS, the ECAT LSO PET/CT 16 system utilizes the same scientific technology as the unmodified ECAT LSO PET/CT system and raises no new questions with regard to its safety and effectiveness. Therefore, we believe the modified ECAT LSO PET/CT 16 is substantially equivalent to the unmodified ECAT LSO PET/CT 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

NOV 8 2002

Mr. William Skremsky
Senior Regulatory Affairs Specialist
CTI PET Systems, Inc.
810 Innovation Drive
KNOXVILLE TN 37932

Re: K023518
Trade/Device Name: ECAT LSO PET/CT 16
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: October 18, 2002
Received: October 21, 2002

Dear Mr. Skremsky:

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

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): K023518

Device Name: ECAT LSO PET/CT 16

Indications for Use:

The ECAT LSO PET/CT 16 tomographic scanner system is a combined positron emission tomography (PET) and X-ray computed tomography (CT) scanner. The ECAT LSO PET/CT 16 scanner is intended to be utilized by appropriately trained health care professionals to 1) image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body; and 2) to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

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(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube and the simultaneous translation of the patient.)

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023518