NOV 2 5 2002

K023768

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:	November 8, 2002

Identification of the Product

Device Proprietary Name:	PET/CT Patient Handling System (PHS)
Common Name:	Patient Bed
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
PHS for ECAT PET/CT	CTI PET Systems (CPS)	K002715
PHS for ECAT LSO PET/CT	CTI PET Systems (CPS)	K013504
PHS for ECAT LSO PET/CT 16	CTI PET Systems (CPS)	K023518

Device Description and Comparison to the Unmodified Device

The subject device is the patient handling system (PHS) or patient bed that is used with the currently marketed CPS ECAT PET/CT scanners. The ECAT PET/CT, ECAT LSO PET/CT and ECAT LSO PET/CT 16 systems are combined positron emission tomography (PET) and X-ray computed tomography (CT) scanners. These three dual modality PET/CT tomographs all utilize the same basic patient handling system (PHS) to support and move the patient through the patient port in the scanner gantry. Currently, vertical positioning of the patient on the bed of these PET/CT scanners is only possible when the PHS bed is fully retracted out of the patient port.

The proposed modification for the PHS used on these three PET/CT scanners, which consists of two added footswitches and revised PHS controller firmware, will enable the system operator to raise or lower the PHS bed a limited distance when the bed and patient are in the scanner field of view (FOV), inside the patient port. This modification will allow the operator to more accurately position the patient in the FOV without having to first retract the bed and patient completely out of the patient port.

Intended Use

The PET/CT Patient Handling System is used to support and move a patient through the PET/CT scanner while CT and PET diagnostic studies are performed on the patient.

Safety and Effectiveness

The PET/CT Patient Positioning System, with the proposed modification for the patient positioning enhancement described in this 510(k), 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 modified PET/CT Patient Positioning System has been tested by CPS and found to meet its predetermined safety and performance requirements.

Substantial Equivalence Determination

In the opinion of CPS, the PET/CT Patient Positioning System, incorporating the described patient positioning enhancement modification, utilizes the same scientific technology as the unmodified version and raises no new questions with regard to its safety and effectiveness. Therefore, we believe the modified Patient Positioning System is substantially equivalent to the unmodified version with respect to design, material and composition, energy source, and safety characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 5 2002

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

Re: K023768
Trade/Device Name: PET/CT Patient Handling System (PHS)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: November 8, 2002
Received: November 12, 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): K023768

Device Name: PET/CT Patient Handling System (PHS)

Indications for Use:

The PET/CT Patient Handling System (PHS) is a system component of CPS ECAT PET/CT tomographic scanner systems, which are combined positron emission tomography (PET) and X-ray computed tomography (CT) scanners. The PET/CT Patient Handling System is used to support and move a patient through the PET/CT scanner while CT and PET diagnostic image data are being acquired from the patient.

The ECAT PET/CT scanners are 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 these systems 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.)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023768

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)