K050509

MAR 2 5 2005

510(K) SUMMARY

(As required by 21 CFR 807.87(h))

Identification of Submitter

Submitter: M. Alaine Medio, RAC
Senior Regulatory Affairs Specialist
CTI Molecular Imaging, Inc.
810 Innovation Drive
Knoxville, TN 37932

Telephone Number: (865)218-2703
Fax Number: (865)218-3019

Date of Submission:

Identification of the Product

Device Proprietary Name: LSO PET/CT HiRez Series

Common Name: Combination Positron Emission Tomography (PET) and Computed Tomography (CT) Systems

Classification Name: Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to which Equivalence is Claimed

Device	Manufacturer	510(k) Number
LSO PET/CT HiRez and HiRez16	CTI PET Systems (CPS)	K033431
LSO PET/CT HiRez 64	CTI PET Systems (CPS)	K042467

Device Description:

The CPS LSO PET/CT Hi-Rez series of scanners are combined Positron Emission Tomography and X-Ray Computed Tomography scanners. These systems are designed for whole-body oncology, neurology and cardiology examinations. They provide registration and fusion of high-resolution metabolic and anatomic information from the two major components of each system, the LSO HiRez PET scanner and the Siemens Somatom CT (either Emotion or Sensation depending on the specific model).

The combined PET/CT scanner is intended for use as a clinical, whole-body oncology machine with high-end spiral CT and PET performance. The CT component provides fast, quiet attenuation correction for PET studies as well as precise anatomical reference through fused PET and CT images. In addition, the PET / CT system maintains independent functionality of the PET and CT scanning systems, allowing for most standard stand-alone CT and PET clinical diagnostic protocols to be available as well.

Changes incorporated in this system are the result of a cost reduction effort combined with changes that allow the "look" of the gantry to be modified easily. Additional changes were incorporated to improve manufacturability and serviceability as well as to deal with parts obsolescence. These changes were limited to the PET gantry as well as the Patient Handling System (PHS). The CT portion of this system is unmodified from the previously commercially available systems.

Indications for Use:

The CPS LSO PET/CT HiRez Series Scanners are combined positron emission tomography (PET) and X-ray computed tomography (CT) scannesr. The LSO 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.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2005

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

Re: K050509
Trade/Device Name: LSO PET/CT
HiRez Series
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed
tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography
x-ray system
Regulatory Class: II
Product Code: KPS and JAK
Dated: February 28, 2005
Received: March 1, 2005

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 (Premarket Approval), 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

INDICATIONS FOR USE FORM

510(k) Number (if known): K050509

Device Name: LSO PET/CT HiRez Series

Indications for Use:

The CPS LSO PET/CT HiRez Series Scanners are combined positron emission tomography (PET) and X-ray computed tomography (CT) scannesr. The LSO 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.

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(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 K050509