JUN - 8 1998

K981027

510(k) Summary of Safety and Effectiveness as required by 21CFR 807.87(h)

Identification of Submitter

Submitter: William Skremsky
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Date of preparation: March 16, 1998

Identification of the Product

Device Proprietary Name: E.CAM LSO 311 PET/SPECT System
Common Name: Nuclear Medicine Gamma/PET Camera
Classification Name: Emission Computed Tomography System per 21CFR 892.1200

Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
IP500 Nuclear Camera	Siemens Medical Systems	K952109
E.CAM Coincidence Mode Option	Siemens Medical Systems	K970627
ICON Computer System	Siemens Medical Systems	K914350
ECAT EXACT & ECAT EXACT HR+	CTI PET Systems	K962797
ECAT PET Scanner System & Software V7.1	CTI PET Systems	K974256

Device Description

The E.CAM LSO 311 PET/SPECT system is a dual detector head nuclear camera having the purpose of performing a full range of nuclear medicine procedures, including:

1) static, dynamic, whole body, and gated planar single photon procedures;
2) dynamic, whole body, and gated single photon emission computed tomography (SPECT) procedures; and
3) static, dynamic, whole body, and gated coincidence positron emission tomography (PET) procedures.

The E.CAM LSO 311 system comprises the following components: gantry and patient table mechanical components, computer system (hardware and software), and dual detector heads. Additional features of the system include attenuation correction capabilities and the ability to upgrade existing Siemens E.CAM cameras in the field to the E.CAM LSO 311 configuration.

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Indications for Use

The Siemens/CPS E.CAM LSO 311 PET/SPECT System is intended to be utilized by appropriately trained health care professionals to image and measure the distribution of injected single photon radiopharmaceuticals and positron emitting radiopharmaceuticals in humans for use in the determination of various metabolic and physiologic functions within the human body and in the diagnosis of certain disease conditions in various organs, tissues and other anatomical structures.

Comparison with Predicate Devices

The E.CAM LSO 311 system is essentially a modified and enhanced version of the Siemens IP500 E.CAM gamma camera and E.CAM Coincidence Mode design and similar products from other vendors, which permits the imaging of positron emitting isotopes in coincidence mode in addition to single photon emitters in the single photon mode. In addition, this new PET/SPECT tomograph utilizes many hardware and software components from currently produced CTI PET Systems (CPS) PET scanners such as the ECAT EXACT and ECAT EXACT HR+. The E.CAM LSO 311 system optimizes the clinical usability of coincidence detection imaging, by enhancing the trues count rate and sensitivity performance of the camera, while still retaining optimum single photon capabilities.

Summaries of Studies

Initial investigation indicates that the CPS E.CAM LSO 311 PET/SPECT System will be capable of performing static, dynamic, whole body and gated planar single photon imaging procedures, as well as single photon emission computed Tomography (SPECT) procedures and positron emission tomography (PET) procedures utilizing a new combination LSO and NaI(TI) crystal detector system developed by CPS.

Conclusion

In the opinion of CTI PET Systems, the E.CAM LSO 311 System is substantially equivalent to the currently distributed Siemens IP500 Gamma Camera System and the associated E.CAM coincidence option. We believe the E.CAM LSO 311 is also substantially equivalent to the Siemens/CPS ECAT EXACT and EXACT HR+ PET systems. The E.CAM LSO 311 has the same intended use and has many of the same technological characteristics as those devices. We do not believe the E.CAM LSO 311 System design raises any new safety and effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 1998

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

Re: K981027
E.CAM LSO 311 PET/SPECT System
Dated: March 16, 1998
Received: March 19, 1998
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Skremsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: E.CAM LSO 311 PET/SPECT System

Indications For Use:

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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 X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981027