K032063

AUG 1 8 2003

510(k) Summary

PEM 2400 PET Scanner

Classification Name: PET Scanner
21 CFR 892.1200

PEM Technologies, Inc.
7617 Standish Place
Rockville, MD 20855

Phone: (301) 315-2007
Fax: (301) 564-5386

Contact: Irving Weinberg MD PhD
Prepared: June 30, 2003

A. LEGALLY MARKETED PREDICATE DEVICES

The intended use of the PEM 2400 PET Scanner device is equivalent to the predicate PET scanner devices listed below, all of which are classified as Emission Computed Tomography devices under 21 CFR 892.1200.

Device	Manufacturing	510(k) Number
GE 2048 PET Scanner	GE Medical Systems	K914267
ECAT ART-LSO PET Scanner	CTI PET Systems, Inc.	K003241
ECAT PET/CT PET Scanner	CTI PET Systems, Inc.	K002715

B. DEVICE DESCRIPTION

The PEM 2400 PET Scanner is a high spatial resolution small field-of-view PET imaging system specifically developed for close-range spot imaging. The PEM 2400 PET Scanner is a partial-ring PET scanner, equipped with lutetium-containing gamma-ray detectors, which collects gamma rays emitted by injected positron-emitting radiopharmaceuticals, and generates images corresponding to concentration of these radiopharmaceuticals in the body. The PEM 2400 PET scanner is designed to collect gamma rays from a patient's body part with high efficiency. In order to achieve this high efficiency, the detectors should be positioned as close as possible to the body part under examination. The PEM 2400 PET Scanner can display images obtained from a digital imaging modality for correlative purposes.

C. INTENDED USE

The PEM 2400 PET Scanner is intended for medical purposes to image and measure the distribution of injected positron emitting radiopharmaceuticals in human beings for the purpose of determining various metabolic and physiologic functions within the human body.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The predicate GE 2048 PET Scanner (K914267) is unable to image the entire body, and is designed to place gamma-ray detectors in close proximity to a body part (e.g., the patient's head). The PEM 2400 PET Scanner is substantially equivalent to the GE 2048 PET Scanner in these two aspects (limitation and proximity to a single body part). The predicate ECAT PET/CT PET Scanner (K002715) provides correlative data from a device previously cleared for marketing solely for x-ray imaging (K991764). The PEM 2400 PET Scanner is similarly enabled for correlation with images from x-ray imaging devices. The predicate ECAT ART-LSO PET Scanner (K003241) contains only two detector heads (each of which uses fast scintillator materials), as does the PEM 2400 PET Scanner.

The PEM 2400 PET Scanner is a medical device and has the same indications-for-use statement as the predicate devices. The device also has the same technological characteristics as the predicate devices. Since a comparison of the descriptive characteristics of the proposed and predicate devices may not be sufficiently precise to assure equivalence, performance data are provided. The result of the performance testing (included in this 510(k) submission) demonstrates substantial equivalence, which is the primary basis for 510(k) concurrence.

E. TESTING

In-vitro and in-vivo performance testing were conducted in accordance with the "Guidance for Industry - Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems," issued by FDA on December 3, 1998.

F. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2003

Irving Weinberg, MD, Ph.D.
President
PEM Technologies
7617 Standish Place
ROCKVILLE MD 20855

Re: K032063
Trade/Device Name: PEM 2400 PET Scanner
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: June 30, 2003
Received: July 9, 2003

Dear Dr. Weinberg:

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 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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K032063

Device Name: PEM 2400 PET Scanner

Indications for Use: The PEM 2400 PET Scanner is intended for medical purposes to image and measure the distribution of injected positron emitting radiopharmaceuticals in human beings 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032063