AUG 21 2008 K082244

Toshiba America Medical Systems, Inc.
510(k) Pre-market Notification; PCA-8000A Mark II

510(k) Summary

Date:	August 1, 2008
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Paul Biggins, Director Regulatory Affairs (714)730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	PCA-8000A, Mark II, Pet/CT System
Common Name:	Emission Computed Tomography System Scanner, Computed Tomography, X-Ray [Fed. Reg. No. 892.1200, Pro. Code: 90KPS] [Fed. Reg. No. 892.1750, Pro. Code: 90JAK]
Regulatory Class:	II
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Predicate Device(s):	GE Discovery VCT; K050559 Toshiba, TSX-201A, Aquilion LB K050458
Reason for Submission	New Device

Device Description:
The PCA-8000A consists of an integrated multi-slice CT system and a Positron Emission Topography Scanner. This system uses CT images to correct for non-uniform attenuation of the PET images. CT images and PET images are integrated to provide localization of emission activity. This system is capable of imaging with all available PET tracers and CT contrast agents. The system will display anatomical and functional information via the integrated graphical display system. The CT portion of the system can be used as a standalone head and whole body CT system.

Summary of Intended Uses:
This device is intended to acquire PET images of any desired region of the whole body simultaneously with CT images of the same region (to be used for attenuation correction or image fusion), to detect the location of a positron emitting radiopharmaceutical in the body

with obtained images. This device is to be used by a trained health care professional to gather metabolic and functional information from the distribution of the radiopharmaceutical in the body for the assessment of metabolic and physiologic functions. This information can assist in the research, diagnosis, therapeutic planning and therapeutic outcome assessment of (but not limited to) cancer, cardiovascular disease and brain dysfunction. Additionally, this device can function independently as a whole body multi-slice CT scanner.

Technological Characteristics:
This device employs similar materials and processes as found in the predicate device. All portions of this device have been designed and manufactured in accordance with the requirements of the applicable portions of ISO 60601and its collateral standards.

Safety and Effectiveness Concerns:
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR § 1020.30 and 1020.33, that apply to this device, will be met and reported via a an initial report. Additionally this system is in conformance with the applicable parts of the IEC 60601-1 {applicable portions}; IEC 60601-2-28, IEC 60601-2-32, and IEC 60601-2-44. - Medical Device Safety standards.

Substantial Equivalence:
This device provides the same indications for use as the predicate device and utilizes technologies and materials that are similar in nature. Toshiba America Medical Systems, Inc. is of the opinion that device is substantially equivalent to those devices already marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2008

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K082244
Trade/Device Name: PCA-8000A Mark II, PET/CT System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 7, 2008
Received: August 8, 2008

Dear Mr. Job:

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 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

510(k) Number (if known): K082244

Device Name: PCA-8000A, Mark II, PET/CT System

Indications for Use:

This device is intended to acquire PET images of any desired region of the whole body simultaneously with CT images of the same region (to be used for attenuation correction or image fusion), to detect the location of a positron emitting radiopharmaceutical in the body with obtained images. This device is to be used by a trained health care professional to gather metabolic and functional information from the distribution of the radiopharmaceutical in the body for the assessment of metabolic and physiologic functions. This information can assist in the research, diagnosis, therapeutic planning and therapeutic outcome assessment of (but not limited to) cancer, cardiovascular disease and brain dysfunction. Additionally, this device can function independently as a whole body multi-slice CT scanner.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 K082244