DEC 23 1998

K983514

510(k) Summary

Date:	September 10, 1998
Submitter's Name: **Submitter's Address:**	Toshiba America Medical Systems, Inc. P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Donelle Krajewski, Regulatory Affairs Specialist, (714)730-5000, Extension 4121
Device Proprietary Name: **Classification Name:** **Common Name:**	Positron Kit, Model NSCO-050A Emission Computed Tomography System Gamma Camera Option [Fed. Reg. No. 892.1200, Pro. Code: 90 KPS]
Predicate Devices:	Siemens E.CAM Coincidence Mode Option
Reason for Submission	New option for existing product

Description of this Device:

The Positron Kit, Model NSCO-050A reconstruction software option will be installed into the GMS-5500A/UI image processor, which is part of the E.CAM dual-detector digital gamma camera system.

Summary of Intended Uses:

This Positron Kit, Model NSCO-050A, will make it possible to perform coincidence planar or SPECT studies using positron nuclides (mainly FDG-type, PET radiopharmaceuticals) without using collimators. Toshiba America Medical Systems, Inc. believes that this device is safe and effective in that it offers no new intended uses that are not in use on existing marketed devices.

Technological Characteristics:

This device employs the same technological characteristics as the predicate device. Both systems employ the use of software to allow positron imaging by coincidence. Positron nuclide imaging is well understood and is documented in peer reviewed scientific publications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Donelle Krajewski
Regulatory Affairs Specialist
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
P.O. Box 2068
Tustin, CA 92781-2068

Re: K983514
Toshiba's Positron Kit, Model NSCO-050A
Dated: September 10, 1998
Received: October 7, 1998
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Krajewski:

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 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). 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,

Capt. Daniel G. Schultz, M.D.
Acting 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): K983514

Device Name: Toshiba's Positron Kit, Model NSCO-050A

Nuclear Medicine Device

Indications For Use: To detect or image the distribution of radionuclides in the body or organ, using the following technique(s).

		YES	NO	Energy Range (keV)
A.	Planar Imaging		X	
B.	Whole Body Imaging		X	
C.	Tomographic Imaging (SPECT) for non Positron Emitter		X	
D.	Positron Imaging by Coincidence	X		Camera range increases to 560 keV
E.	Positron Imaging without Coincidence		X	
F.	Positron Whole Body Imaging by Coincidence	X		Camera range increases to 560 keV

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510 (k) Number: K983514