

DEC 23 1998

510(k) Summary

Date: September 10, 1998

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: Donelle Krajewski, Regulatory Affairs Specialist,
(714)730-5000, Extension 4121

Device Proprietary Name: Transmission Kit, Trans-CT, Model NSTR-050A
Classification Name: Emission Computed Tomography System
Common Name: Gamma Camera Option
[Fed. Reg. No. 892.1200, Pro. Code: 90 KPS]

Predicate Devices: Siemens E.CAM Profile Attenuation Correction (K963983)

Reason for Submission New option for existing product

Description of this Device:

The Transmission Kit, Trans-CT for E.CAM, Model NSTR-050A is a software option for the ECAM gamma camera system that will be used to process and reconstruct acquired transmission and emission data. This software will be installed into the GMS-5500A/UI image processor which is part of the ECAM system. When the external flood source of this system is combined with a parallel-hole collimator, this system can generate anatomic frame attenuation maps and perform attenuation corrections on SPECT images.

Summary of Intended Uses:

This device is designed to be used in combination with E.CAM gamma camera systems to process and reconstruct acquired transmission CT data (TCT) and emission data. When the external flood source of the E.CAM Profile system is combined with a parallel-hole collimator, this software can generate anatomic frame attenuation maps and perform attenuation corrections on SPECT images. The intended uses of this product are commensurate with other products currently in the marketplace.

Technological Characteristics:

This software employs the same technological characteristics as the predicate device. Both systems employ the use of a transmission source to provide the attenuation map. This attenuation map is then used to perform attenuation corrections on SPECT images along with scatter correction. Attenuation correction using transmission systems is well understood and is documented in peer reviewed scientific publications.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983516
Toshiba's Transmission Software, Trans-CT for E.CAM,
Model NSTR-050A
Dated: September 10, 1998
Received: October 7, 1998
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Krajewski:

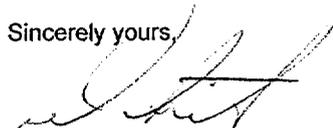
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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):

K 983516

Device Name:

Toshiba's Transmission Software, Trans-CT for E.CAM, Model NSTR-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		50-400
D.	Positron Imaging by Coincidence			
E.	Positron Imaging without Coincidence		X	
F.	Positron Whole Body Imaging by Coincidence		X	

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

✓
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510 (k) Number:

K 983516