K031469

510(k) Summary

MAY 22 2003

Date:	April 8, 2003
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: (714) 730-5000	Paul Biggins, Regulatory Affairs Manager,
Establishment Registration Number:	2020563
Device Proprietary Name:	TSX-101A/7, Aquilion Super 4 Multislice CT Scanner
Common Name:	Scanner, Computed Tomography, X-Ray [Fed. Reg. No. 892.1750, Pro. Code: 90JAK]
Regulatory Class:	II (per 21 CFR 892.1750)
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Predicate Device(s): Multislice kit	TSX-101A Aquilion CT w/ CGS-22A
Reason For Submission	Modification of cleared device

Description of this Device:
The Aquilion Super 4 CT Scanner is similar to the Aquilion Multislice CT scanner. The major difference between the two devices is a change of hardware in the computational subsystem and an improved patient couch. This device uses the same software and scanning hardware as the predicate device.

Summary of Intended Uses:
This device is designed to produce cross-sectional images of a human body by reconstruction of x-ray transmission data from the same axial plane taken at different angles. These images have been proven to be clinically useful in the diagnosis of spine and head injuries, intracranial tumors, blood clots in the brain, eye trauma, soft tissue lesions in the extremities, gastrointestinal lesions, abdominal and pelvic malignancies, and hepatic metastases. CT is also used to evaluate intestinal obstructions, assess intra-abdominal abnormalities and to examine musculoskeletal degeneration. This device employs no intended uses that are not in cleared devices already found in the marketplace.

Technological Characteristics:
This device employs the same technological characteristics as the predicate device, differing only in the specifics of subassembly component composition. Both of these systems employ the use of high frequency x-ray controllers to generate x-radiation from the x-ray tube. The x-ray transmission data is detected by the x-ray detector and is reconstructed by the computer. This device produces digital images that can be filmed or electronically stored for future review.

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, which apply to this upgrade, will be met and reported via a supplement to the initial report for the predicate device. Additionally this system is in conformance with the applicable parts of the IEC-60601 - Medical Device Safety standards.

Substantial Equivalence:
Based upon the above considerations TAMS believes that the Aquilion Super 4 CT System is substantially equivalent to the TSX-101A, Aquilion CT scanner. The major difference is a change in the configuration of the computational subsystem.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2003

Toshiba America Medical Systems, Inc.
c/o Ms. Laura Danielson
Responsible Third Party Official
TÜV America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K031469
Trade/Device Name: Aquilion Super 4 CT Systems, TSX-101A/7
Regulation Number: 21 CFR §892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: May 8, 2003
Received: May 9, 2003

Dear Ms. Danielson:

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

510(k) Number (if known): K03 1469

Device Name: Aquilion Super 4 CT System; TSX-101A/7

Indications for Use:

X-ray imaging of whole body - Computerized Tomography
Including:
Axial
Volumetric (Helical)
CT Fluoroscopy

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031469

(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)