3/19/99

K990134

510(k) Summary

Date:	11 January 1999
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, Regulatory Affairs Specialist, (714)730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	Multislice Upgrade Kit for Aquilion CT Scanner, TSX-101A (Aquilion/Multi)
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):	Toshiba TSX-101A, Aquilion [K982265]
Other Similar Devices:	Siemens SOMATOM Plus 4 with Volume Zoom [K982349] Elscint Volumax CT scanner [K982060] GE LightSpeed QXi [K980176]
Reason For Submission	Modification of cleared device

Description of this Device:
The Multislice kit is an upgrade to previously cleared Aquilion CT Scanner, TSX-101A; [K982265]. This upgrade will allow for the collection of multiple axial slices in one scan. This is accomplished by employing multiple solid state detectors. This methodology allows for the acquisition of high resolution slices will maintaining the speed required to reduce anatomical motion artifacts.

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 device 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 two dimensional, black and white image 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, that 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 this upgrade package, Multislice CT, CGS-22A, is substantially equivalent to the Aquilion CT scanner. Other devices on the market that share the characteristics of this device are the Siemens SOMATOM Plus 4 with Volume Zoom [K982349], the Elscint Volumax CT scanner [k982060], and the GE LightSpeed QXi [K980176].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1999

Paul Biggins
Regulatory Affairs Specialist
Toshiba America Medical Systems, Inc.
2441 Michelle Dr.
P.O. Box 2068
Tustin, CA 92781

Re: K990134
Multislice Upgrade Kit for Aquilion CT Scanner
Dated: January 11, 1999
Received: January 14, 1999
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Biggins:

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): K990134

Device Name: Multislice Upgrade kit (CGS-22A) for the Aquilion CT Scanner TSX-101A

Indications for Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990134

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