

K97 3908

DEC 22 1997

## 510(k) Summary

**Date:** 20 August 1997

**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:** Auklet CT Scanner, TSX-003A

**Common Name:** Scanner, Computed Tomography, X-Ray  
[Fed. Reg. No. 892.1750, Pro. Code: 90JXD]

**Regulatory Class:** II (per 21 CFR 892.1750)

**Predicate Device:** Toshiba TSX-002A, Xvision [K941745]

**Reason For Submission** New Product

### Description of this Device:

The Auklet is a whole body CT Scanner that employs slip ring technology which allows continuous rotation of the x-ray tube and x-ray detector. The x-ray detector collects transmission data as it and the x-ray tube rotate 360 degrees axially around a human body. Computer controlled data processing reconstructs the transmission data into a two dimensional image representing a "slice" of the body. As is common with today's CT Scanner, the Auklet has the capability to acquire volumetric (helical) data by initiating table movement during data acquisition. This data can be reconstructed per the operator's preference, to include three dimensional rendering of the patient data. This device incorporates a standard x-ray tube and xenon gas filled x-ray detector for the acquisition of data. The microprocessor based computer, hard disk storage of software and data, and display electronics are mature technologies that are standard to and well known throughout the medical device industry.

### 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 image 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 system 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. Both of these devices produce two dimensional, black and white image that can be filmed or electronically stored for future review.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K973908  
TSX-003A Auklet CT Scanner  
Dated: October 13, 1997  
Received: October 14, 1997  
Regulatory class: II  
21 CFR 892.1750/Procode: 90 JAK

DEC 22 1997

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 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 requirement, 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/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
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): K973908

Device Name: Auklet CT Scanner TSX-003A

Indications for Use:

X-ray imaging of whole body - Computerized Tomography

Including:

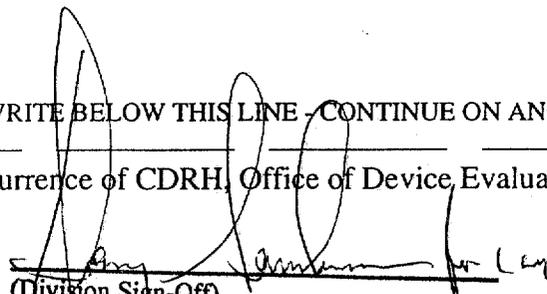
Axial

Volumetric (Helical)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K973908

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use