NOV 1 8 2004

K043111

510(k) Summary

Date:	October 27, 2004
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, Senior Regulatory Affairs Manager, (714) 730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	PlaqueView (a.k.a. SurePlaque) CSPV-001A
Common Name:	Scanner, Computed Tomography, X-Ray [Fed. Reg. No. 892.1750, Product 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):	General Electric Perfusion CT 2 [K0041267] Siemens Perfusion CT [K990426]
Reason For Submission	Modification of Cleared Device

Description of this Device:
The CSPV-001A is an image analysis software package, that will be applied to the Toshiba TSX-101A (Aquilion) CT scanner, that allows the user to process acquired image data. The package allows visualization of the data in image map formats. Additionally, the package allows the display of numeric data via the image analysis software that is integral to the package. The software is post processing and does not control the x-ray features of the system.

Summary of Intended Uses:
PlaqueView/SUREPlaque is a post processing software that facilitates faster and easier visualization of cardiovascular lumens, vessel walls, plaques, and other bodies. This software can lay vessels out in curved planar reformats, cross sectional views, and maximum intensity projection views. Color based on a density range can then be applied to the various parts of the anatomy for easier reading.

Technological Characteristics:
This package is similar in uses and applications as those of the predicate devices. The main difference is in the method used to obtain the final results. Both this and the predicate devices are used as post-processing software applied to images collected by the parent CT Scanner.

Safety and Effectiveness Concerns:
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. 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, PlaqueView/SurePlaque, Model Number CSPV-0001A is substantially equivalent to the predicate devices. This package and the predicate devices are all post-processing and provide the same features of visualization and numeric data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2004

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K043111
Trade/Device Name: PlaqueView, Model Number CSPV-001A
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: November 8, 2004
Received: November 10, 2004

Dear Mr. Job:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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

Indications for Use

510(k) Number (if known): K043111

Device Name: PlaqueView, Model Number CSPV-001A

Indications for Use:

The PlaqueView (SurePlaque) tool kit application software package is intended to assist trained physicians in the stratification of patients identified to have coronary disease (CAD). This software post processes images obtained using a multi-detector Aquilion CT. The package provides tools for the measurement and visualization (color coded maps) of coronary arteries.

(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)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043111