K072693
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Toshiba America Medical Systems, Inc.
510(k) Pre-market Notification; CSNP-001A Neuro Package

510(k) Summary

NOV - 1 2007

Date:	September 20, 2007
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, Director Regulatory Affairs (714)730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	CSNP-001A Neuro Package
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):	CSCP-001A Cerebral Bloop Perfusion Analysis Package
Reason For Submission	New device

Description of this Device:

This device is a post processing package that allows the user to process dynamic volume sets using a Time Density Curve. The package allows visualization of the data in image map format. Additionally, the software provides numeric data via image analysis software.

Summary of Intended Uses:

This device is application software that permits cerebral perfusion imaging based upon dynamic volume sets. The software allows for visualization of apparent blood flow in the brain tissue and pictorially illustrates perfusion parameters (CBP – cerebral blood perfusion, CBV – cerebral blood volume, MTT – mean time to transit, TTP – time to peak of the time density curve, and DLY – delay of each voxel curve from the arterial curve). This device, when used by a trained physician, will assist in the assessment of the type and extent of cerebral perfusion disturbances. Additionally, the software allows for measurement of various values such as mean value, standard deviation, area and distance.

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Technological Characteristics:

This device is similar to the predicate device in uses and applications. The primary difference is in the method used to obtain final results. Both devices are post processing software packages.

Safety and Effectiveness Concerns:
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. Additionally this device is in conformance with the applicable parts of the IEC 60601-1 international safety standard.

Substantial Equivalence:
Based upon the above considerations TAMS believes that this device, CSNP-001A Neuro Package, is substantially equivalent to the predicate device and other devices already marketed in the US. This device and other similar marketed devices are post processing software that provide visual and numeric data. Additionally, this device has the same indications of previously marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Toshiba America Medical Systems. Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 24th Street NW
BUFFALO MN 55313

NOV - 1 2007

Re: K072693
Trade/Device Name: CSNP-001A, NeuroPackage
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK and LLZ
Dated: October 22, 2007
Received: October 23, 2007

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 (PMA), 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K072693

Device Name: CSNP-001A, NeuroPackage

Indications for Use:

The CSNP-001A is a post processing package that has the capability to perform brain perfusion studies to include whole brain studies, when used by a trained physician, by using data that is acquired on a time sequential basis. This package provides the physician with the following information that can then be measured and analyzed in the assessment of brain trauma or stroke:

TDC (time density curve)
CBF: Blood flow in the capillary vessels of the cerebral tissues.
CBV: Blood volume in the capillary vessels of the cerebral tissues.
MTT: Mean transit time of blood in the capillary vessels f the cerebral vessels.
TTP: Time to peak of the TDCs.
DLY: Delay of each voxel curve from the arterial curves.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072693