Submitter Information

SUBMITTER:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44080-2371 ph: (330) 425-1313 fax: (330) 963-0749
CONTACT:	Douglas J. Thistlethwaite
DATE:	April 9, 2009

JUN 15 2009

Device Name

CLASSIFICATION NAME:	Computed tomography x-ray system
CLASSIFICATION NUMBER:	Sec. 892.1750
TRADE/PROPRIETARY NAME:	guideShot
PREDICATE DEVICE(S):	Hitachi Presto (CXR4) Computed Tomography X-ray System, 510(k) K040902
	Hitachi ECLOS Computed Tomography X-ray System, 510(k) K071806

Device Intended Use

The CXR4 and ECLOS Computed Tomography Systems with guideShot Option are x-ray imaging devices that produce cross-sectional images of the body at different angles. The systems reconstruct, process, display, and store the collected images. The guideShot Option adds a remote in-room display and controls to support interventional imaging. The device output can provide an aid to diagnosis when used by a qualified physician.

Device Description

Function

The CXR4 and ECLOS is a multi-slice computed tomography system that uses x-ray data to produce cross-sectional images of the body at various angles. The guideShot Option adds a remote monitor and controls at the patient table to allow the operator to initiate data collection and to view resulting CT images in order to support interventional procedures.

Scientific Concepts

The CXR4 and ECLOS system uses "third generation" CT technology, where the x-ray tube and detector assemblies are mounted on a frame that rotates continuously around the patient using slip ring technology. The solid-state detector assembly design collects up to 16 slices of data simultaneously depending on the model. The x-ray sub-system features a high frequency generator, x-ray tube, and collimation system that produces a fan beam x-ray output. The system can operate in a helical (spiral) scan mode where

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the patient table moves during scanning. As the x-ray tube/detector assembly rotates around the patient, data is collected at multiple angles.

The collected data is then reconstructed into cross-sectional images by a high-speed reconstruction sub-system. The images are displayed on a computer workstation, stored, printed, and archived as required. The workstation is based on current PC technology using the Windows™ operating system.

Physical and Performance Characteristics

The CXR4 and ECLOS systems consist of a gantry, operator's workstation, patient table, high-frequency x-ray generator, and accessories. The guideShot option adds a remote monitor and footswitch to control acquisitions and display images in the scan room. The system performance is similar to the predicate device.

Performance Comparison

Because the CXR4 and ECLOS with guideShot Option and the predicate device are both Hitachi designs, they were subjected to the same non-clinical evaluations as stipulated in 21 CFR 1020.33(c). Evaluations include: dose profile, image noise, modulation transfer function (MTF), slice thickness and sensitivity profile, slice plane location, and CT dose index.

The evaluation results of the CXR4 and ECLOS with guideShot Option were comparable to the predicate device and support our conclusion that the system is substantially equivalent.

Device Technological Characteristics

The CXR4 and ECLOS with guideShot Option acquires data in the same manner as the predicate device. Physically, the CXR4 and ECLOS with guideShot Option is very similar to the predicate device. The key differences are the ability to initiate a scan and display data in the scan room.

The ability to collect and display image on an in-room monitor does not change the essential characteristics of the finished images. The operation of the system is virtually identical to the predicate because guideShot simply adds remote display and controls to the predicate device. The CXR4 and ECLOS operating system software is essentially the same, as well as the user interface. The patient table design and gantry controls are unchanged.

In conclusion, the CXR4 and ECLOS with guideShot Option is technologically equivalent in concept, function, and performance to the predicate device.

Conclusions

The CXR4 and ECLOS with guideShot Option has been developed and validated according to applicable standards. Testing has proven that the system is safe and effective for the indicated use. Risk and hazard analysis shows that there are no new safety issues associated with this system as compared with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Mr. Doug Thistlewaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K091103
Trade/Device Name: guideShot Option, CXR4 Computed X-ray System and guideShot Option, ECLOS Computed Tomography X-ray System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: April 9, 2009
Received: April 16, 2009

Dear Mr. Thistlewaite:

This letter corrects our substantially equivalent letter of June 15, 2009.

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 (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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K091103

Device Name: guideShot Option, CXR4 Computed Tomography X-ray System

Indications for Use:

The CXR4 Computed Tomography System with guideShot Option are x-ray imaging devices that produce cross-sectional images of the body at different angles. The systems reconstruct, process, display, and store the collected images. The guideShot Option adds a remote in-room display and controls to support interventional imaging. The device output can provide an aid to diagnosis when used by a qualified physician.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091103