APR 2 1 2004

K040902

HITACHI

HITACHI MEDICAL SYSTEMS AMERICA, INC.
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510(k) Summary

Submitter Information

Submitter: Hitachi Medical Systems America, Inc.
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Contact: Douglas J. Thistlethwaite

Date: February 24, 2004

Device Name

Device Name:	Computed tomography x-ray system
Trade/Proprietary Name:	Presto
Common Name:	Computed Tomography X-ray System
Classification Name:	System, X-Ray, Tomography, Computed
Classification Number:	Sec. 892.1750

Predicate Device

Predicate Device: Hitachi Pronto CT, 510(k) K014240

Device Description

Function

The Presto is a multi-slice computed tomography system that uses x-ray data to produce cross-sectional images of the body at various angles.

Scientific Concepts

The Presto 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 4 slices of data simultaneously. 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 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 Presto system consisting of a gantry, operator's workstation, patient table, high-frequency x-ray generator, and accessories. The system performance is similar to the predicate device.

Performance Comparison

Because the Presto 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 Presto were comparable to the predicate device and support our conclusion that the Presto CT system is substantially equivalent.

Device Intended Use

The Presto Computed Tomography system is an x-ray imaging device that produces cross-sectional images of the body at different angles. The system reconstructs, processes, displays, and stores the collected images. The device output can provide an aid to diagnosis when used by a qualified physician.

Device Technological Characteristics

The Presto CT system acquires data in the same manner as the predicate device. Physically, the Presto is very similar to the predicate device. The key differences are the ability to collect 4 slices in a single scan as well as improvements in overall technology.

The ability to collect 4 slices in a single scan allows overall scan time to be decreased but does not change the essential characteristics of the finished images. The predicate is a single slice design, meaning that if an area of 16 mm is to be examined in 2 mm increments, the x-ray tube must scan the patient 8 times, collecting 2 mm of data for each scan, to produce 8 total images. In the Presto's 4 slice design, the system need only to scan 2 times, collecting 8 mm of data during each scan. The x-ray beam is collimated to allow the exposure of 4 slices simultaneously, and the data collection system collects all 4 slices. Since the data collection system processes the data in 2 mm increments, the system produces 8 images as before, but during a shorter time.

The operation of the system is virtually identical to the predicate because both systems were produced using the same essential design concepts. The Presto operating system software is essentially the same, as well as the user interface. The patient table design is the same, with the exception that the weight limit was increased somewhat. Gantry controls provide the same features as the predicate, but the control layout was updated.

Despite these differences, the Presto CT system is technologically equivalent in concept, function, and performance to the predicate device.

Conclusions

The Presto CT system 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.

Replacement page inserted 29 March 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 2004

Hitachi Medical Systems America, Inc.
c/o Mr. Daniel Lehtonen
Staff Engineer – Medical Devices
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01779

Re: K040902
Trade/Device Name: Presto Computed Tomography X-ray System
Regulation Number: 21 CFR §892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: April 6, 2004
Received: April 7, 2004

Dear Mr. Lehtonen:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known): K040902

Device Name: Presto Computed Tomography X-ray System

Indications for Use:

The Presto Computed Tomography system is an x-ray imaging device that produces cross-sectional images of the body at different angles. The system reconstructs, processes, displays, and stores the collected images. The device output can provide an aid to diagnosis when used by a qualified physician.

(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 K040902

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Prescription Use _____ OR Over-the-Counter Use _____