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OCT 2 0 2003

HITACHI

HITACHI MEDICAL SYSTEMS AMERICA, INC.
1959 Summit Commerce Park
Twinsburg, Ohio 44087-2371
Tel.: 330.425.1313
Fax: 330.425.1410

510(k) Summary

Submitter Information

Submitter: Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44080-2371
ph: (330) 425-1313
fax: (330) 425-1410

Contact: Douglas J. Thistlethwaite

Date: August 29, 2003

Device Name

Device Name:	Extraoral source x-ray system
Trade/Proprietary Name:	CB MercuRay
Common Name:	Dental X-ray System
Classification Name:	Extraoral source x-ray system.
Classification Number:	Sec. 872.1800

Predicate Device

Predicate Device: NewTom QR-DVT 9000, 510(k) K003787

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Device Description

Function

The CB MercuRay system is an x-ray device that uses a cone beam with a 360°rotational sequence, providing two-dimensional images and three-dimensional volume reconstructions for ENT and dentomaxillofacial applications.

Scientific Concepts

The CB MercuRay system incorporates conebeam technology. The x-rays are continuously emitted in a cone shape during rotation providing image data of 288 views. Projection images acquired are applied with offset correction and logarithmic conversion. The data are then applied with corrections for detector sensitivity, geometric distortion and runover of the subject. The acquired data can be presented as 2-dimensional images or can be reconstructed as a 3-dimensional 512^3 matrix image.

Physical and Performance Characteristics

The system consists of two main components; scanner and console. The scanner contains a U-arm with an x-ray generator with a 9" or 12" Image Intensifier and a 100M pixel CCD camera horizontally facing each other. The U-arm rotates horizontally around the patient's head. Data acquisition is performed with the patient in an upright, seated position. Images can be printed or exported on standard computer media.

Device Intended Use

The CB MercuRay system is an x-ray imaging device that provides two-dimensional images and three-dimensional volume reconstructions. The system specifically images the head and neck areas, which includes ENT and dentomaxillofacial areas, for use in planning and diagnostic support.

Device Technological Characteristics

The CB MercuRay system acquires data in the same manner as the predicate device. Physically, the significant difference is that the CB MercuRay positions the patient in an upright, seated position during acquisition. The predicate device acquires data with the patient lying down on a table. The remaining differences are increased options and features with the CB MercuRay such as four different fields of view and increased 3D features within the viewing software.

Despite these small differences, the CB MercuRay system is technologically equivalent in concept, function, and performance to the predicate device.

Conclusions

The CB MercuRay system has been developed and validated according to applicable standards. Testing has proven that the CB MercuRay 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

OCT 2 0 2003

Hitachi Medical Systems America, Inc.
% Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K033248
Trade/Device Name: CB MercuRay Dental Cone-Beam X-Ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: October 6, 2003
Received: October 7, 2003

Dear Mr. Sherratt:

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): K033248

Device Name: CB MercuRay Dental Cone-beam X-ray System

Indications for Use:

The Hitachi CB MercuRay system is an x-ray imaging device that uses a cone beam with a 360°rotational sequence, providing two-dimensional images and three-dimensional volume reconstructions. The system specifically images the head and neck areas, which includes ENT and dentomaxillofacial areas, for use in planning and diagnostic support.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033248

Prescription Use ✓ OR Over-the-Counter Use _____