K974077

J.Morita USA, Inc.
Versaview Panoramic/Cephalometric Dental X-Ray System
510(k) Summary

Submitter's Name, Address, and Telephone Number

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JAN 20 1998

Contact Person

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as Regulatory Counsel to J.Morita USA, Inc.

Date Prepared

October 21, 1997

Name of Device

Versaview Panoramic-Cephalometric Dental X-Ray System

Classification Name

Extraoral Dental X-Ray Device with Cephalometer

Common Name

Panoramic-Cephalometric Dental X-Ray System

Predicate Devices

Kaycor International's Panoura ULTRA Pan/Ceph X-Ray Unit
Kaycor International's Panoura-10C Pan/Ceph X-Ray Unit
J.Morita USA, Inc.'s Versaview Panoramic Dental X-Ray System

Intended Use

J.Morita USA, Inc.'s Versaview Panoramic-Cephalometric Dental X-Ray System ("Panoramic/Cephalometric System") is intended to take panoramic and cephalometric dental x-rays including anterior-posterior, posterior-anterior, and submentovortex views.

Substantial Equivalence

The Panoramic/Cephalometric System is a modification of J.Morita USA, Inc.'s Versaview Panoramic Dental X-Ray System. The modified device consists of a x-ray control unit, x-ray upright assembly, x-ray head, collimator, and cephalometer. The upright assembly and cephalometer have a patient positioning assembly which is used to position and hold the patient's head during a dental x-ray. The patient positioning assembly on the upright assembly consists of a forehead stabilizer, zygoma stabilizer, bite block, bite block cover, and chin rest. The patient positioning assembly on the cephalometer consists of forehead stabilizer, rearhead stabilizer, and ear rod.

To take a x-ray, the dentist positions the patient in one of the patient positioning assemblies and loads the film cassette on the cassette holder. If taking panoramic x-rays, the dentist adjusts the exposure voltage and amperage. If taking a cephalometric x-ray, the dentist adjusts the exposure voltage and time. The exposure amperage in cephalometric x-ray mode is automatically set at 10 milliamps. The dentist presses the emission button on the control unit's handswitch to take the x-ray. After the exposure is complete, the patient can move away from the x-ray.

The Panoramic/Cephalometric System is substantially equivalent to the predicate devices because they have the same intended use, principles of operation and technological characteristics. For instance, the devices have similar x-ray outputs, focal spot sizes, total filtration, and maximum tube voltage and current. In addition, the Panoramic/Cephalometric System and the Panoramic System have the same patient contacting materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1998

J. Morita USA, Inc.
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Suite 500 North
Washington, DC 20005
Attn: Terry G. Mahn

Re: K974077
Versaview Panoramic-Cephalometric Dental
X-Ray System
Dated: October 28, 1997
Received: October 29, 1997
Regulatory class: II
21 CFR 872.1800/Procode: 90 EHD

Dear Mr. Mahn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Versaview Panoramic-Cephalometric Dental X-Ray System

Indications For Use:

To take panoramic and cephalometric dental x-rays including anterior-posterior, posterior-anterior and submentovortex views.

(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, ENT,
and Radiological Devices
510(k) Number K974077

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

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