MAY 2 9 2003

K030699

510(k) SUMMARY

J. Morita Manufacturing Corporation's
Veraviewepocs Panoramic/Cephalometric X-ray Unit
With Digital Image Function

Name of Device and Name/Address of Sponsor

Trade or Proprietary Name:	Veraviewepocs Panoramic/Cephalometric X-ray Unit With Digital Image Function
Common Name:	Extraoral Source X-ray with Cephalometric Capability
Classification Name:	Extraoral Source X-ray System and Cephalometer
Product Code :	EHD (Extraoral Source X-ray System) EAG (Cephalometer) MUH (Extraoral Source Digital X-ray System)

J. Morita Mfg. Corp.
680 Higashihama Minami-cho, Fushimi-ku,
Kyoto 612-8533, Japan

Contact Person: Hideaki Okuda, Senior Executive Director
Date Prepared: February 28, 2003

Intended Use

The Veraviewepocs Panoramic/Cephalometric X-ray Unit With Digital Image Function is an extraoral source X-ray unit that is used for dental radiographic examination and diagnosis of teeth, jaw, and oral structure by exposing an X-ray image receptor to ionizing radiation, with an optional cephalometric capability, and a digital imaging capability for taking both panoramic and cephalometric images.

Technological Characteristics and Substantial Equivalence

The Veraviewepocs Panoramic X-ray Unit is an FDA-cleared extraoral source X-ray unit that is used for dental radiographic examination and diagnosis of teeth, jaw, and oral structure by exposing an X-ray image receptor to ionizing radiation (K#013955). A cephalometric capability was added to this device in 2002 (K#021372). The device is now being modified to add a digital imaging capability.

The modified Veraviewepocs is substantially equivalent, for purposes of the FDA's medical device regulations, to Instrumentarium Corporation Imaging Division's (i) Orthoceph OC100 extraoral x-ray unit for cephalometric radiography (K#930338 and K#973642) (ii) Orthopantomograph OP100 extraoral x-ray unit for cephalometric radiography (also cleared under K#973642), and (iii) Orthoceph OC100 D for digital panoramic and cephalometric radiography (K#001439). The modified Veraviewepocs has the same general intended use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices. Although there are minor difference in the characteristics of the modified Veraviewepocs and the predicate devices, these differences do not raise new questions of safety or efficacy.

The software used in the modified Veraviewepocs has been successfully validated by Morita. The software validation report describes the development process for the device's software/firmware; the software change control and code revision procedures; the system and software requirements; the software handling and storage procedures; a hazard analysis; and a software/firmware certification that the company followed the above-described procedures and policies.

The modified Veraviewepocs was tested to ensure compliance with UL2601-1 and IEC 60601-1, and it complied with the applicable requirements. The modified Veraviewepocs will be tested and will comply with the applicable requirements of 21 C.F.R. Subchapter J prior to marketing. The modified Veraviewepocs also passed the image quality testing.

The modified Veraviewepocs complies with the applicable thermal, mechanical, and electrical safety requirements of UL2601-1 and IEC 60601-1, and will comply with the applicable requirements of 21 C.F.R. Subchapter J prior to marketing.

The modified Veraviewepocs uses biocompatible metals and plastics on any body contacting surfaces, such as the temple stabilizers and covers, ear rods, chin rests, patient handles, and front/rear head stabilizers. The metals and plastics have been widely used in other medical applications in which the metal or plastic is in body contact, including oral contact.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2003

J. Morita Manufacturing Corporation
% Mr. Keith A. Barritt
Regulatory Attorney
Fish & Richardson P.C.
1425 K Street, N.W., 11th Floor
WASHINGTON DC 20005

Re: K030699
Trade/Device Name: Veraviewepocs Panoramic/ Cephalometric X-Ray Unit
Regulation Number: 21 CFR 872.1830
Regulation Name: Cephalometer
Regulatory Class: II
Product Code: 90 EAG
Dated: March 5, 2003
Received: March 6, 2003

Dear Mr. Barritt:

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): K030699

Device Name: Veraviewepocs Panoramic/Cephalometric X-ray Unit With Digital Image Function

Indications For Use:

The Veraviewepocs Panoramic/Cephalometric X-ray Unit With Digital Image Function is an extraoral source X-ray unit that is used for dental radiographic examination and diagnosis of teeth, jaw, and oral structure by exposing an X-ray image receptor to ionizing radiation, with an optional cephalometric capability, and a digital imaging capability for taking both panoramic and cephalometric images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

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David R. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030699