K053220

JAN 6 2006

510(k) SUMMARY

J. Morita USA Inc.'s Veraview IC 5

XDP1

1. Submitter Name and Address with Phone/Fax :

Registration No. 2081055	Registration No. 3002807636
Initial Distributor:	Manufacturer:
J. Morita USA, Inc.	J. MORITA MFG. CORP.
9 Mason	680 Higashihama Minami-cho
Irvine, CA 92618	Fushimi-ku, Kyoto
USA	Japan 612-8533
Telephone: 949-581-9600	+81-75-611-2141
Facsimile: 949-581-9688	+81-75-605-2354

2. Contact Person

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

3. Date summary prepared: October 17, 2005

4. Device Name:

Trade or Proprietary Name:	Veraview IC 5 Model XDP1
Common Name:	Dental Panoramic X-ray Unit
Classification Name:	Extraoral Source dental X-ray System (21CFR872.1800)
Product Code :	MUH

5. Substantial Equivalency is claimed against the following device:

Veraviewepocs Model VE from J. MORITA MFG.CORP.
510k # : K030699

00214

6. Description of the device:

The Veraview IC5 Model XDP1(hereinafter XDP1) is an extraoral source dental panoramic x-ray system intended to produce x-rays for dental radiographic examination and diagnosis of disease of the teeth, jaw and oral structure.

The XDP1can be used to take standard panoramic images, Pedodontic panoramic images, and TMJ quadruple images.

This XDP1 is a device modified from the X550P-D-UL which is one of Veraview epocs Model VE (K#030699) of J.MORITA MFG. CORP. Both XDP1and X550P-D-UL are dental panoramic device, XDP1 is provided with automatic exposure control by CCD sensor while the latter is incapable of such automatic exposure control.

Except automatic exposure control, the main hardware is used unchanged in the same way as the previous, and the XDP1 reserves the same general intended use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device, so that the XDP1 is substantially equivalent to Veraviewepocs Model VE (K#030699).

7. Intended Use

The XDP1 is used with the purpose to obtain dental x-ray panoramic tomography pictures by digital processing with a CCD sensor which is capable of electronic imaging over the whole Dento-maxillofacial area such as teeth, periodontal tissues or chin- bone etc.

8. Safety and effectiveness of the device

This Model XDP1 is a modified device from the Veraviewepocs Model VE (K#030699) of J.MORITA MFG. CORP. by eliminating the film image receptor to CCD sensor. However, not only the main hardware is used unchanged in the same way as the predicate device, but also the XDP1 reserves the same general intended use, similar principles of operation, and similar technological characteristics, so that the XDP1 is substantially equivalent to the Veraviewepocs Model VE (K#030699).

Although there are minor differences in the characteristics between the Model XDP1 and the predicate device as is shown at Table-1 and Table-2, these differences do not raise new questions of safety or effectiveness because they are able to be considered as almost same .

Table-1 Comparison summary chart

	This new submission	Predicate	Difference
Name of the model	XDP1	X550P-D-UL	Different
Manufacturer	J.MORITA MFD. CORP.	J.MORITA MFD. CORP.	Identical
Construction	Rotating arm and base	Rotating arm and base	Similar
Image Receptor	X-ray CCD sensor	X-ray film and X-ray CCD sensor	Different
Performance spec.	International standards	International standards	Similar
Mechanical	XDP1 mechanism	X550P mechanism	Similar
Electrical	XDP1 electric circuit	X550P electric circuit	Similar
Software	XDP1software	X550P software	Different
Testing	VDE	VDE	Similar

Table-2 Comparison summary table

FDA file reference number 510k number ; K030699

Attachment inside notification submission file 510k FDA website print out

Model name of Predicate Device	X550P-D-UL
510(k) number of Predicate Device	K030699
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indication for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Similar
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Identical
Anatomical sites	Similar
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Identical
Electrical safety	Similar
Thermal safety	Identical
Radiation safety	Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

J. Morita USA, Inc.
c/o Mr. Keith A. Barritt
Attorney
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
WASHINGTON DC 20005

Re: K053220
Trade/Device Name: Veraview IC 5(XDP1)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: November 15, 2005
Received: November 17, 2005

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): ~~unknown~~ K053220

Device Name: XDP1

Indications For Use:

The Veraview IC 5 (XDP1) is an extraoral source x-ray unit that is used for dental radiographic examination and diagnosis of teeth, jaw, oral structure, TM-joints and skull by exposing an X-ray image receptor to ionizing radiation.

Prescription Use ✓ 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)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053220