K 122806

Section 6- 510(k) Summary

MAR 0 8 2013

a. Owner/Company name, address

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c. Date prepared

September 5, 2012

d. Name of device

Trade Name:	IMAGEWORKS PANOURA
Common Name:	Extraoral source x-ray system
Classification Name:	System, x-ray, extraoral source, digital
Classification Regulation:	21 CFR 872.1800

e. Predicate devices

The IMAGEWORKS PANOURA is substantially equivalent to the following legally marketed device:

510(k):	K111231
Trade name:	PANOURA 18S
Product code:	MUH

510(k):	K093683
Trade name:	ORTHOPANTOMOGRAPH OP300
Product code:	MUH

The predicate devices are hereinafter called "the PANOURA 18S (k111231)" or "the ORTHOPANTOMOGRAPH (k093683)" , respectively, in this application.

f. Description of the device

The IMAGEWORKS PANOURA is dental panoramic and cephalometric device and intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images of examined volume for the reconstruction of 3D view. The IMAGEWORKS PANOURA is equipped with an X-ray generator and a Sensor unit at Arm unit supported by Column unit and Sliding body unit. While rotating around the patient's teeth and jaw, the IMAGEWORKS PANOURA irradiates X-ray and detects X-ray absorbed data at the Sensor unit multiple times. Detected multiple data are transferred to an image processing unit and the data are superimposed with appropriate shift value according to the X-ray moving speed from the arm rotation to acquire image.

g. Statement of Intended Use

The IMAGEWORKS PANOURA dental panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images of examined volume for the reconstruction of 3D view. The device must only be operated and used by dentists and other legally qualified professionals.

h. Statement of substantial equivalence

The IMAGEWORKS PANOURA is modified from the PANOURA 18S (k111231) by adding 3D imaging. The characteristics except 3D imaging of the IMAGEWORKS PANOURA are identical to those of the PANOURA 18S (k111231).

Regarding intended use of the IMAGEWORKS PANOURA, 3D imaging is added to intended use of the PANOURA 18S (k111231). However, patient population and the fundamental technologies of the IMAGEWORKS PANOURA are identical to those of the PANOURA 18S (k111231).

3D imaging of the IMAGEWORKS PANOURA is similar to that of the ORTHOPANTOMOGRAPH (k093683). 3D image is produced by reconstruction of X-ray projection images. Intended Use of the IMAGEWORKS PANOURA is similar to that of the ORTHOPANTOMOGRAPH

(k093683) because the characteristics of the IMAGEWORKS PANOURA are similar to the ORTHOPANTOMOGRAPH (k093683). The similarities of the IMAGEWORKS PANOURA to the ORTHOPANTOMOGRAPH (k093683) are;

- Intended use
- Operational characteristics
- Ionizing radiation
- Cephalometric radiogram
- Panoramic images
- 3D Imaging

In order to evaluate safety and effectiveness of the IMAGEWORKS PANOURA, software verification/validation, performance testing, and risk analysis were performed. In conclusion, those testing and analysis demonstrated that the IMAGEWORKS PANOURA did not raise any new safety or effectiveness concerns compared to the PANOURA 18S (k111231) and the ORTHOPANTOMOGRAPH (k093683).

i. Comparison table

Table 6-1 compares the characteristics between the IMAGEWORKS PANOURA, the PANOURA 18S (k111231), and the ORTHOPANTOMOGRAPH (k093683).

Table 6-1. Comparison Table

Device Characteristics			IMAGEWORKS PANOURA	PANOURA 18S (k111231)	ORTHOPANTOMOGRAPH (k093683)
Intended Use			The IMAGEWORKS PANOURA dental panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images of examined volume for the reconstruction of 3D view. The device must only be operated and used by dentists and other legally qualified professionals.	The Panoura 18S dental panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images. The device must only be operated and used by dentists and other legally qualified professionals.	The Orthopantomograph OP300 dental panoramic, cephalometric and cone beam computed tomography x-ray device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D x-ray images as well as X-ray projection images of an examined volume for the reconstruction of a 3D view. The device must only be operated and used by dentists and other legally qualified professionals.
Equipment type			Digital panoramic x-ray equipment	Digital panoramic x-ray equipment	Digital panoramic x-ray equipment
Mode of operation			Continuous operation with intermittent load	Continuous operation with intermittent load	Continuous operation with intermittent load
X-ray tube focal point			0.5 mm×0.5 mm	0.5 mm×0.5 mm	0.5 mm×0.5 mm
X-ray tube cooling method			Oil cooling	Oil cooling	Oil cooling
Nominal maximum electric power (combination of X-ray tube voltage and tube current at maximum output)			0.82kW (82kV, 10mA)	0.82kW (82kV, 10mA)	1.44kW (90kV, 16mA)
Tube voltage			58 - 82kV	58 - 82kV	57 - 90kV
Tube current			2.0 - 10mA	2.0 - 10mA	4 - 16mA
Radiation time	Panoramic	Adult	8, 14, 16s	8, 14, 16s	16.4s
		Child	6.4, 11.2, 12.8s	6.4, 11.2, 12.8s	14.4s
	TMJ		8s	8s	10.6s
	Cephalo / Carpus image acquisition		8 –10 s	8 –10 s	10-20s

Device Characteristics			IMAGEWORKS PANOURA	PANOURA 18S (k111231)	ORTHOPANTOMOGRAPH (k093683)
Radiation time	3D	3D oral	11.5s x 2	-	Small FOV standard resolution: 2.3 s Large FOV standard resolution: 4.9s Small FOV high resolution: 6.1 s Large FOV high resolution:12.6 s
		3D dent	11.5s	-	
Electric power supply resistance			Maximum 0.2 Ω	Maximum 0.2 Ω	Maximum 0.2 Ω
Total filtration			2.5mmAl equivalent or over	2.5mmAl equivalent or over	3.2mm Al equivalent or over
Leakage dose			1.0 mGy/h or less	1.0 mGy/h or less	1.0 mGy/h or less
Leakage dose calculation standards			Tube voltage 82kV, tube current 10mA	Tube voltage 82kV, tube current 10mA	Tube voltage 90kV, tube current 4mA
Image magnification	Panoramic		1.2 to 1.29	1.2 to 1.29	1.3
	TMJ		1.2 to 1.29	1.2 to 1.29	1.23
	Cephalo		1.1	1.1	1.14
	3D		1.0	-	1.0
Rated power	Number of phases		Single phase	Single phase	Single phase
	Frequency		50 / 60 Hz	50 / 60 Hz	50 / 60Hz
	Voltage		AC100V – 120V / AC220V - 240V	AC100V – 120V / AC220V - 240V	AC100 - 240V (Selectable)
	Input	110VAC	2.0kVA	2.0kVA	1.65kVA
		230VAC	2.0kVA	2.0kVA	2.3kVA
Classification			Class I, Type B	Class I, Type B	Class I, Type B
Up-and-down stroke			800 mm (short type: 400 mm)	800 mm (short type: 400 mm)	800 mm
Weight			140kg Standing position, wall mount (with 3D detector)	125kg Standing position wall mount	200kg (Panoramic)
			135kg Standing position, wall mount (short type) (with 3D detector)	120kg Standing position wall mount (short type)	
			165 kg Standing position, base mount with an optional base (in the case of wide base: +5kg) (with 3D detector)	150 kg (with an optional base)	
			160kg Standing position, base mount (short type) with an optional base (in the case of wide base: +5kg) (with 3D detector)	145kg Standing position base mount short type with an optional base/ 150kg with wide base	

Device Characteristics		IMAGEWORKS PANOURA	PANOURA 18S (k111231)	ORTHOPANTOMOGRAPH (k093683)
Weight		180kg Standing position wall mount (with Cephalo)	190kg Standing position wall mount (with Cephalo)	240kg (Cephalo)
		175kg Standing position, base mount (short type) (with Cephalo) (with 3D detector)	185kg Standing position wall mount short type (with Cephalo)	
		205kg Standing position, base mount with an optional base (with Cephalo) (in the case of wide base: +5kg) (with 3D detector)	215kg Standing position base mount with Cephalo and optional base	
		200kg Standing position, base mount (short type) (with Cephalo) (in the case of wide base: +5kg) (with 3D detector)	210kg Standing position base mount short type with Cephalo and optional base/ 215kg with wide base	
Size		2209 x 846 x 1192mm(Standing position wall mount)	2209 x 849 x 1192mm(Standing position wall mount)	2410 x 830 x 1126mm (standard column)
		2209 x 1835 x 1192mm(Standing position wall-mount with Cephalo)	2209 x 1759 x 1192mm(Standing position wall-mount with Cephalo)	2410 x 1931 x 1193 mm (with Cephalo)
SID/SOD (Panoramic)		485mm / 350mm	485mm / 350mm	500mm(SID)
SID/SOD (Cephalo)		1650mm / 1500mm	1650mm / 1500mm	1745mm / 1520mm
SID/SOD (3D)		570mm / 350mm	-	unknown
Operating environment	Temperature	10 to 40°C	10 to 40°C	10 to 35°C
	Relative humidity	30 to 75% (no condensation)	30 to 75% (no condensation)	max 85%
EMC Classification		ClassA	ClassA	Class B
Target angle		15 degrees	15 degrees	5 degrees
Positioning laser lights		laser light (CLASS 2 LASER PRODUCT)	laser light (CLASS 2 LASER PRODUCT)	laser light (CLASS 1 LASER PRODUCT)
		IEC 60825-1:1993+A1:1997+A2:2001	IEC 60825-1:1993+A1:1997+A2:2001	IEC 60825-1:1993+A1:1997+A2:2001
Cephalometric radiogram	Scanning method	Horizontal scan, synchronized sensor and secondary slot motion	Horizontal scan, synchronized sensor and secondary slot motion	Horizontal scan, synchronized sensor and secondary slot motion
	Scanning time	8 - 10s	8 - 10s	10 - 20s
Panoramic image receptor	Sensor unit	Pan sensor or interchangeable Cephalo sensor	Pan sensor or interchangeable Cephalo sensor	Pan sensor or interchangeable Cephalo sensor
	Technology	CMOS	CMOS	CMOS

Device Characteristics		IMAGEWORKS PANOURA	PANOURA 18S (k111231)	ORTHOPANTOMOGRAPH (k093683)
Panoramic image receptor	Image pixel size	100 x 100 µm	100 x 100 µm	100 x 100 µm
	Image field height	151mm / 1510pixels	151mm / 1510pixels	151mm / 1480pixels
Cephalometric image receptor	Sensor unit	interchangeable Cephalo sensor	interchangeable Cephalo sensor	interchangeable Cephalo sensor
	Technology	CMOS	CMOS	CMOS
	Image pixel size	100 x 100 µm	100 x 100 µm	100 x 100 µm
	Image field height	226.6mm / 2266pixels	226.6mm / 2266pixels	226mm / 2232pixels
	Image field width in LA view	254mm	254mm	260mm, maximum 170mm, minimum
	Image field width in PA view	203.2mm	203.2mm	200mm
3D image receptor	Sensor unit	3D sensor	-	3D sensor
	Technology	CMOS	-	CMOS
	Image pixel size	100 x 100 µm	-	200µm
	Image field height	99.2mm / 992pixels	-	61 mm

j. Risk Analysis

The IMAGEWORKS PANOURA was evaluated in accordance with ISO14971:2007. The risk management of the device was deemed satisfactory.

k. Bench Testing

THE YOSHIDA DENTAL MFG. CO., LTD has performed bench tests regarding laser safety to ensure safety and effectiveness, verify conformity with IEC 60825-1.

The laser system of the IMAGEWORKS PANOURA is identical to that of the PANOURA 18S (K111231). Therefore, the test report for IEC 60825-1 for the PANOURA 18S (K111231) is used as the test report for the IMAGEWORKS PANOURA.

The software of the IMAGEWORKS PANOURA has been validated according to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

EMC, Electric safety, and X-ray radiation safety are confirmed in accordance with IEC60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, and IEC 60601-2-32.

l. Conclusion

The IMAGEWORKS PANOURA is modified from the PANOURA 18S (k111231) by adding 3D imaging. The characteristics except 3D imaging of the IMAGEWORKS PANOURA are identical to those of the PANOURA 18S (k111231). The IMAGEWORKS PANOURA has similar intended use and operational and technological characteristics to the ORTHOPANTOMOGRAPH (k093683). The performance test results indicate that the IMAGEWORKS PANOURA meets the requirements of recognized consensus or voluntary standard. Based on the information presented above regarding substantial equivalence to the PANOURA 18S (k111231) and the ORTHOPANTOMOGRAPH (k093683), THE YOSHIDA DENTAL MFG. CO., LTD. concludes that the IMAGEWORKS PANOURA is substantially equivalent to the PANOURA 18S (k111231) and the ORTHOPANTOMOGRAPH (k093683), and does not raise any new questions regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ms. Izumi Maruo
MIC International
4-1-17 Hongo, Bunkyo-ku
TOKYO 113-0033
JAPAN

March 8, 2013

Re: K122806
Trade/Device Name: ImageWorks Panoura
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 25, 2013
Received: March 1, 2013

Dear Ms. Maruo:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122806

Device Name: IMAGEWORKS PANOURA

Indications for Use:

The IMAGEWORKS PANOURA dental panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images of examined volume for the reconstruction of 3D view. The device must only be operated and used by dentists and other legally qualified professionals.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K122806