January 31, 2019

The Yoshida Dental Mfg. Co., Ltd.
Hidenori Watanabe
Regulatory Affairs
1-3-6, Kotobashi
SUMIDA-KU, 130-8516 JAPAN

Re: K182198
Trade/Device Name: Panoura X-ERA PF/NF/MF
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: December 14, 2018
Received: December 20, 2018

Dear Hidenori Watanabe:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182198

Device Name
Panoura X-ERA PF/NF/MF

Indications for Use *(Describe)*
The Panoura X-ERA PF/NF/MF 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 Panoura X-ERA PF/NF/MF dental panoramic and cephalometric device is intended for general populations. The device must only be operated and used by dentists and other legally qualified professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K182198

510(k) Summary

a. Owner/Company name, address

THE YOSHIDA DENTAL MFG. CO., LTD.
1-3-6, Kotobashi, Sumida-ku
Tokyo
130-8516, Japan

- Contact person

Hidenori Watanabe
International Regulatory Affairs
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Email: hi-watanabe@yoshida-net.co.jp

b. Date prepared

September 20, 2018

c. Name of device

Trade Name:	Panoura X-ERA PF/NF/MF
Regulation Name:	Extraoral source x-ray system
Classification Name:	System, x-ray, extraoral source, digital
Classification Regulation:	21 CFR 872.1800
Product Code:	MUH

d. Predicate devices

Panoura X-ERA PF/NF/MF is substantially equivalent to the following legally marketed device:

510(k):	K122806
Trade name:	IMAGEWORKS PANOURA
Regulation Name:	Extraoral source x-ray system
Classification Regulation:	21 CFR 872.1800
Product code:	MUH

e. Description of the device

The Panoura X-ERA PF/NF/MF dental panoramic and cephalometric device is modified from the IMAGEWORKS PANOURA (K122806).

The Panoura X-ERA PF/NF/MF 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.

Panoura X-ERA PF/NF/MF consists of a scanner, which is used for generating X-ray and detecting image data, and a Console, which is used for operating the scanner and managing the data. The scan data acquired by the scanner will be transferred to the Console. The Console is new software and classified as moderate level concern. 3D Viewer will then perform the image analysis or image edition such as creating cross-section diagram.

3D sensor is not installed for Panoura X-ERA PF. Medium FOV sensor is installed for Panoura X-ERA NF. Large FOV sensor is installed for Panoura X-ERA MF.

f. Indications for Use

The Panoura X-ERA PF/NF/MF 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 Panoura X-ERA PF/NF/MF dental panoramic and cephalometric device is intended for general populations. The device must only be operated and used by dentists and other legally qualified professionals.

g. Statement of substantial equivalence

Comparative Information

The Panoura X-ERA PF/NF/MF is modified from the IMAGEWORKS PANOURA (K122806).

Indications for use of the Panoura X-ERA PF/NF/MF is identical to that of the IMAGEWORKS PANOURA (K122806). Patient population and the fundamental technologies of the proposed device are identical to those of the predicate device.

The similarities are;

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

The main changes of Panoura X-ERA PF/NF/MF from the predicate device are software and addition of an 3D sensor. The proposed device's software for image acquisition setting and creating images is entirely different form the predicate device's software.
Although the other 3D sensor is identical to the 3D sensor of the predicate device, the scanning mode setting is changed from the predicate device. The scanning mode for Panoura X-ERA PF/NF/MF was fast mode which is changed from fine mode for the predicate device. Following table shows comparison for 3D sensor and scanning mode between the proposed and predicate devices.

Table 1 Comparison for 3D sensor and scanning mode

	Proposed device*		Predicate device
Device name or model	Panoura X-ERA MF	Panoura X-ERA NF	IMAGEWORKS PANOURA (K122806)
Flat panel detector	C10900D-40	C10901D-40	
Manufacturer	Hamamatsu Photonics KK		
Scanning mode	Fast mode	Fast mode	Fine mode
Image pixel size (μm)	200 x 200	200 x 200	100 x 100
Effective photosensitive area (mm)	121.6 x 123.2	99.2 x 67.2	
Number of pixels	608 x 616	496 x 336	1008 x 682
Readout circuit	Change amplifier array		
Video data format	13 bit	13 bit	12 bit
Scintillator	Directory deposited CsI		
Frame rate (frame/s)	10-35	10-60	10-30
Noise (electrons)	2900	2200	1300

Saturation charge (M electrons)	10.5	10.5	2.2
Sensitivity (LSB/mR)	6000	6000	3500
Resolution (Line pairs/mm)	2.5	2.5	4.5
Dynamic range	3600	4700	1700

* 3D imaging is not available for Panoura X-ERA PF.

Following is comprehensive comparison table.

Table 2. Comparison Table

Device Characteristics		Panoura X-ERA PF/NF/MF			IMAGEWORKS PANOURA (K122806)	
Indications for Use		The Panoura X-ERA PF/NF/MF 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 Panoura X-ERA PF/NF/MF dental panoramic and cephalometric device is intended for general populations. The device must only be operated and used by dentists and other legally qualified professionals.			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.	
Equipment type		Digital panoramic x-ray equipment			Same	
Mode of operation		Continuous operation with intermittent load			Same	
X-ray tube focal point		0.2 mm×0.2 mm			0.5 mm×0.5 mm	
X-ray tube cooling method		Oil cooling			Same	
Nominal maximum electric power (combination of X-ray tube voltage and tube current at maximum output)		0.36kw（90kV, 4mA）			0.82kW (82kV, 10mA)	
Tube voltage		70 – 90 kV			58 – 82 kV	
Tube current		2 – 4 mA			2.0 – 10 mA	
Radiation time	Panoramic	Regular	7.0, 12.0s		Adult	8, 14, 16s
		Low dose	5.9、10.1s		Child	6.4, 11.2, 12.8s
	TMJ	3.4s x 2			8s	
	Bitewing	3.4s x 2			-	
	Cephalo / Carpus image acquisition	8.0, 10.0, 12.0, 15,0s			8 –10s	
Radiation time	3D	Panoura X-ERA MF	Large FOV Low dose mode	12.0s, 20.0s	3D oral mode: 11.5s x 2 3D dent mode: 11.5s	
			Medium FOV Low dose mode	12.0s, 20.0s		

			Medium FOV High quality mode	12.0s, 16.0s	
			Small FOV sensor High quality mode	12.0s, 16.0s	
	3D	Panoura X-ERA NF	Medium FOV Low dose mode	12.0s, 20.0s	
			Small FOV sensor High quality mode	12.0s, 16.0s	
Electric power supply resistance		Maximum 0.2 Ω			Same
Total filtration		2.5mmAl equivalent or over			Same
Leakage dose		1.0 mGy/h or less			Same
Leakage dose calculation standards		Tube voltage 90kV, tube current 4mA			Tube voltage 82kV, tube current 10mA
Image magnification	Panoramic	1.3 to 1.4			1.2 to 1.29
	TMJ	1.3 to 1.4			1.2 to 1.29
	Bitewing	1.3 to 1.4			-
	Cephalo	1.1			1.1
	3D	1.0			1.0
Rated power	Number of phases	Single phase			Same
	Frequency	50 / 60 Hz			Same
	Voltage	AC100V – 120V / AC220V - 240V			Same
	Input	110VAC	1.5kVA		2.0kVA
		230VAC	1.5kVA		2.0kVA
Classification		Class I, Type B			Same
Up-and-down stroke		800 mm			800 mm (short type: 400 mm)
Weight		150kg: Standing position wall-mount: Panoramic type			140kg Standing position, wall mount (with 3D detector)
		205kg: Standing position base-mount: Panoramic type			135kg Standing position, wall mount (short type) (with 3D detector)
		155kg: Standing position wall-mount: Large FOV 3D type			165 kg Standing position, base mount with an optional base (in the case of wide base: +5kg) (with 3D detector)

		210kg: Standing position base-mount: Large FOV 3D type	160kg Standing position, base mount (short type) with an optional base (in the case of wide base: +5kg) (with 3D detector)
Weight		190kg: Standing position wall-mount: Medium FOV 3D type	180kg Standing position wall mount (with Cephalo)
		255kg: Standing position base-mount: Large FOV 3D Cephalometric 2-sensor type	175kg Standing position, base mount (short type) (with Cephalo) (with 3D detector)
		190kg: Standing position wall-mount: Medium FOV 3D Cephalometric 2-sensor type	205kg Standing position, base mount with an optional base (with Cephalo) (in the case of wide base: +5kg) (with 3D detector)
		255kg: Standing position base-mount: Medium FOV 3D Cephalometric 2-sensor type	200kg Standing position, base mount (short type) (with Cephalo) (in the case of wide base: +5kg) (with 3D detector)
		190kg: Standing position wall-mount: Cephalometric 1-sensor type	-
		250kg: Standing position base-mount: Cephalometric 1-sensor type	
		195kg: Standing position wall-mount: Large FOV 3D Cephalometric 1-sensor type	
		255kg: Standing position base-mount: Large FOV 3D Cephalometric 1-sensor type	
		195kg: Standing position wall-mount: Medium FOV 3D Cephalometric 1-sensor type	
		255kg: Standing position base-mount: Medium FOV 3D Cephalometric 1-sensor type	
Size		2300 x 1070 x 1365 mm (Standing position wall-mount)	2209 x 846 x 1192mm (Standing position wall mount)
		2300 x 1860 x 1365 mm (Standing position wall-mount with Cephalo)	2209 x 1835 x 1192mm (Standing position wall-mount with Cephalo)
SID/SOD (Panoramic)		650 mm/435 mm (25.6inch / 17.1inch)	485 mm / 350 mm
SID/SOD (Cephalo)		1650 mm/1500 mm (65.0inch / 59.1inch)	Same
SID/SOD (3D)		670 mm/435 mm (26.4inch / 17.1inch)	570 mm / 350 mm
Operating environment	Temperature	10 to 40°C	Same
	Relative humidity	30 to 75% (no condensation)	Same
EMC Classification		Class A	Same

Target angle		10 degrees		15 degrees
Positioning laser lights		laser light (CLASS 1 LASER PRODUCT)		laser light (CLASS 2 LASER PRODUCT)
		IEC60825-1:2007, IEC60825-1：2014		IEC 60825-1:1993+A1:1997+A2:2001
Cephalometric radiogram	Scanning method	Horizontal scan, synchronized sensor and secondary slot motion		Same
	Scanning time	8 - 15s		8 - 10s
Panoramic image receptor	Sensor unit	Pan sensor or Detachable combination sensor for panorama and cephalometric		Detachable combination sensor for panorama and cephalometric
	Technology	CMOS		Same
	Image pixel size	100 x 100 μm		Same
	Image field height	151mm / 1510 pixels		Same
Cephalometric image receptor	Sensor unit	Detachable combination sensor for panorama and cephalometric		Same
	Technology	CMOS		Same
	Image pixel size	100 x 100 μm		Same
	Image field height	226.6mm / 2266pixels		Same
	Image field width in LA view	254mm		Same
	Image field width in PA view	203.2mm		Same
3D image receptor	Sensor unit	Panoura X-ERA NF	3D sensor	Same
	Technology		CMOS	Same
	Image pixel size		200 x 200 μm (Fast mode)	100 x 100 μm (Fine mode)
	Image field height		99.2mm / 992pixels	Same
	Sensor unit	Panoura X-ERA MF	3D sensor	-
	Technology		CMOS	-
	Image pixel size		200 x 200 μm (Fast mode)	-
	Image field height		121.6 mm/608 pixels	-

Bench Testing

THE YOSHIDA DENTAL MFG. CO., LTD has compared test pattern images acquired using the proposed device with those images acquired using predicate device in accordance with FDA guidance entitled "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices".

The test pattern images of the proposed device and those of the predicate device were equivalent.

THE YOSHIDA DENTAL MFG. CO., LTD has also performed bench testing regarding laser safety to verify conformity with IEC 60825-1:2007 and 2014.

The software of the proposed device 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 IEC 60601-1-2:2007, IEC60601-1:2012, IEC 60601-1-3:2013, IEC60601-1-6:2010, IEC 60601-2-28:2010, IEC 60601-2-54:2015, and IEC 60601-2-63:2012.

Conclusion

The Panoura X-ERA PF/NF/MF is modified from the predicate device. The changed points are evaluated with software validation and bench testing and did not raise new concern. THE YOSHIDA DENTAL MFG. CO., LTD. concludes that the Panoura X-ERA PF/NF/MF is substantially equivalent to the IMAGEWORKS PANOURA (K122806).