J.Morita USA, Inc.
% Keith Barritt
Attorney
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
Washington, DC 20005

December 19, 2017

Re: K171012
Trade/Device Name: Veraview X800
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: March 30, 2017
Received: April 4, 2017

Dear Keith 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. 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Robert Ochs

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K#171012

Device Name
Veraview X800 X-Ray System

Indications for Use *(Describe)*

The Veraview X800 is intended to be used for panoramic tomography including linear tomography and scanogram, cephalometric radiography, and cone beam computed tomography.

The Veraview X800 is an extraoral source X-ray unit that is used for dental and head radiographic examination and diagnosis of teeth, jaw, oral structure, temporomandibular joint, skull including the dento-maxillofacial areas, and hand for maturity assessment, by exposing an X-ray image receptor to ionizing radiation.

The device uses a cone shaped X-ray beam projected onto a flat panel detector, and the examined volume image is reconstructed to be viewed in 2D or 3D viewing stations.

The device is to be operated and used by dentists and other legally qualified professionals for pediatric and adult patients.

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.

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510(k) Summary
J. Morita USA Inc.
Veraview X800
X-ray system for Panoramic, Cephalometric and CBCT imaging

The following information is provided pursuant to 21 CFR 807.92.

807.92(a)(1): Submitter's Name/Address, Contact, and Preparation Date

(i) 510(k) Submitter

Registration No. 2081055
J. Morita USA, Inc.
9 Mason, Irvine, CA 92618, USA
Phone: 949-581-9600
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(ii) 510(k) Submitter Contact

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Washington DC 20005, USA
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(iii) Preparation Date

December 14, 2017

807.92(a)(2): Name of Device

Trade or Proprietary Name:	Veraview X800
Model Name:	X800
Common Name:	Dental Computed Tomography X-ray System imaging
Classification Name:	Computed tomography x-ray system
Device Classification Panel:	Class II, Radiology
Product Code:	OAS
Regulation:	21 CFR 892.1750

807.92(a)(3): Predicate Device

The Veraview X800 is substantially equivalent for purposes of FDA medical device regulations to the following primary predicate device:

Trade or Proprietary Name:	OP300 (K#133544)
Common Name:	Dental panoramic cephalometric and cone beam computed tomography x-ray device
Classification Name:	Computed tomography x-ray system
Device Classification Panel:	Class II, Radiology
Product Code:	OAS
Regulation:	21 CFR 892.1750

K#170813 is a secondary/reference predicate device:

Trade or Proprietary Name:	ORTHOPANTOMOGRAPH™ OP 3D (K#170813)
Common Name:	X-ray, Tomography, Computed, Dental
Classification Name:	Computed tomography x-ray system
Device Classification Panel:	Class II, Radiology
Product Code:	OAS
Regulation:	21 CFR 892.1750

J. MORITA CORP.'s own X550 (K#073696) is a secondary/reference predicate device:

Common Name:	Dental Panoramic/Cephalometric X-ray System with CT Capability
Classification Name:	Extra-oral source dental x-ray system
Device Classification Panel:	Class II, Radiology
Product Code:	MUH
Regulation:	21 CFR 872.1800

807.92(a)(4): Device Description

The Veraview X800 consists of the following components: x-ray arm with extraoral x-ray source assembly faced with x-ray detector, cephalometric support, high-voltage generator, control assembly, patient positioning device, and software containing communication and image construction.

The Veraview X800 has three main radiographic modes as follows:
- Panoramic tomography including linear tomography and scanogram
- Cephalometric radiography
- Cone beam computed tomography

807.92(a)(5): Intended Use

The intended use of the X800 is:

- Panoramic tomography including linear tomography and scanogram
- Cephalometric radiography
- Cone beam computed tomography

The intended use of the primary predicate device is:

> The OP300 dental panoramic, cephalometric and cone beam computed tomography x-ray device is intended for dental radiographic examination 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 is operated and used by qualified healthcare professionals.

Indication for Use

> Veraview X800 is intended to be used for panoramic tomography including linear tomography and scanogram, cephalometric radiography, and cone beam computed tomography. Veraview X800 is an extraoral source X-ray unit that is used for dental and head radiographic examination and diagnosis of teeth, jaw, oral structure, temporomandibular joint, skull including the dento-maxillofacial areas, and hand for maturity assessment, by exposing an X-ray image receptor to ionizing radiation.
>
> The device uses a cone shaped X-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 2D or 3D viewing stations.
>
> The device is to be operated and used by dentists and other legally qualified professionals for pediatric and adult patients.

807.92(a)(6): Technological Characteristics

Comparison tables of the Veraview X800 and (1) the primary predicate K#133544 and reference device K#170813 and (2) the reference device K#073696 appear below:

Comparison table for the primary predicate K133544 and reference K#170813 devices:

		Proposed device	Primary predicate device (ORTHOPANTOMOGRAPH™ OP300, K133544)	Reference predicate device (ORTHOPANTOMOGRAPH™ OP 3D, K170813)
1	Indications for Use/ Intended Use	Veraview X800 is intended to be used for panoramic tomography including linear tomography and scanogram, cephalometric radiography, and cone beam computed tomography. Veraview X800 is an extraoral source X-ray unit that is used for dental and head radiographic examination and diagnosis of teeth, jaw, oral structure, temporomandibular joint, skull including the dento-maxillofacial areas, and hand for maturity assessment, by exposing an X-ray image receptor to ionizing radiation. The device uses a cone shaped X-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 2D or 3D viewing stations. The device is to be operated and used by dentists and other legally qualified professionals for pediatric and adult patients.	The OP300 dental panoramic, cephalometric and cone beam computed tomography x-ray device is intended for dental radiographic examination 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 is operated and used by qualified healthcare professionals.	ORTHOPANTOMOGRAPH™ OP 3D is an x-ray device to take panoramic and 3D images of the craniomaxillofacial complex for use in diagnostic support. ORTHOPANTOMOGRAPH™ OP 3D must only be used and operated by dentist and other qualified professionals

		Proposed device	Primary predicate device (ORTHOPANTOMOGRAPH™ OP300, K133544)	Reference predicate device (ORTHOPANTOMOGRAPH™ OP 3D, K170813)
2	Imaging modes	Panoramic CBCT Cephalometric	Panoramic CBCT Cephalometric	Panoramic CBCT
3	Focal spot	0.5	0.5	0.5
4	Image detector	CMOS Flat Panel +CCD detector (ceph)	CMOS Flat Panel +CMOS detector (Pan/ceph)	CMOS Flat Panel
5	CBCT imaging technique	Reconstruction from 2D images	Reconstruction from 2D images	Reconstruction from 2D images
6	CBCT's Field Of View (cm)	4 x 4 8 x 4, 5, 8 10 x 4, 5, 8 15 x 5, 7.5, 14	5x5 6x8 8x8 8x15 13x15	5 x 5 6 x 9 9 x 11 9 x 14
7	CBCT's total viewing angle	180, 360 degree	360 degree	360 degree
8	CBCT's effective exposure time (s)	Scout: 0.5, 1.0 CBCT: 9.4, 17.9 17.9 x 2 for FOV 15 x 14	1.2 - 12.5	1.7 - 20
9	CBCT Reconstruction Time	1-6 min. (depending on the computer specification)	1-3 min.	1-3 min.
10	Patient's Position	Standing and wheelchair	Standing and wheelchair	Standing and wheelchair
11	System footprint (includes the operator)	H218.5-232.5cm D120cm W140-200 cm	H161-241cm D139cm W97-193 cm	H167-247cm D77-100cm 130 cm
12	Weight	Pan/CBCT 185-190 kg Ceph 220-225 kg	Pan/CBCT 205 kg Ceph 240 kg	100 kg
13	Classification	OAS	OAS	OAS
14	CBCT resolution	Standard, high resolution	Low , standard, high, endo	Low , standard, high, endo

		Proposed device	Primary predicate device (ORTHOPANTOMOGRAPH™ OP300, K133544)	Reference predicate device (ORTHOPANTOMOGRAPH™ OP 3D, K170813)
15	2D imaging programs	Adult Pan, Child Pan, TMJ, BW, Partial Pan	Adult Pan, Child Pan, TMJ, BW, Partial Pan	Adult Pan, Child Pan, TMJ, BW, Partial Pan
16	-	-	-	-
17	CMOS flat panel pixel size	0.1 mm x 0.1 mm	100 μm x 100 μm	99 μm x 99 μm
18	System MTF	2.5 lp/mm @10% FOV 4x4 High Resolution	2.25 lp/mm @10% FOV 5x5 High Resolution	2.2 lp/mm@10% FOV 5x5 High Resolution

Comparison table for the reference predicate K#073696 is as follows:

Item	Device submitted in this 510(k)	Reference device
Product name	Veraview X800	Veraviewepocs
Model	X800	X550
Manufacturer	J. MORITA MFG. CORP.	J. MORITA MFG. CORP.
Indications for use	Veraview X800 is intended to be used for panoramic tomography including linear tomography and scanogram, cephalometric radiography, and cone beam computed tomography. Veraview X800 is an extraoral source X-ray unit that is used for dental and head radiographic examination and diagnosis of teeth, jaw, oral structure, temporomandibular joint, skull including the dento-maxillofacial areas, and hand for maturity assessment, by exposing an X-ray image receptor to ionizing radiation. The device uses a cone shaped X-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 2D or 3D viewing stations. The device is to be operated and used by dentists and other legally qualified professionals for pediatric and adult patients.	The Veraviewepocs 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 including the ENT and dento-maxillofacial areas, by exposing an X-ray image receptor to ionizing radiation. The device uses cone shaped X-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 2D or 3D viewing stations. The device is to be operated and used by dentists and other legally qualified professionals.
Energy used and/or delivered	AC 120 V, 60 Hz	AC 120 V, 60 Hz

Design	Loading factors	Tube Potential: 60-100kV Tube Current: 2-10mA Loading time: max. 18.5s	Tube Potential: 60-90kV Tube Current: 1-10mA Loading time: max. 20.3s
	X-ray tube assembly	Nominal focal spot: 0.5 at target angle Inherent filtration min. 2.5mmAL	Nominal focal spot: 0.5 at target angle Inherent filtration min. 2.5mmAL
	X-ray detector 1	Internal parts code: D001-15038-50* See column in predicate device.	Internal parts code: D001-15038-50* CMOS flat panel Scintillator: CsI Pixel size for Pan: 0.1 mm Pixel size for CBCT: 0.1 mm, 0.2 mm
	X-ray detector 2	Internal parts code: D001-16044-50* CMOS flat panel Scintillator: CsI Pixel size for Pan: 0.1 mm Pixel size for CBCT: 0.1 mm, 0.2 mm	Internal parts code: D00-113030-50* CMOS flat panel Scintillator: CsI Pixel size for Pan and CBCT: 0.2 mm
	X-ray detector 3	Internal parts code: D001-04188-50* See column in predicate device.	Internal parts code: D001-04188-50* CCD line sensor Scintillator: CsI Pixel size for Ceph: 0.1 mm
Soft-ware	Viewer (general purpose viewer: not included in this submission of the device)	Viewer software: 510K number: K073704 Device name: i-Dixel	Viewer software: 510K number: K073704 Device name: i-Dixel

Performance	Panoramic - spatial resolution	Line pair resolution on IEC 61223-3-4: min. 2.5 LP/mm	Line pair resolution: min. 2.5 LP/mm
	Panoramic - noise	Low contrast resolution on IEC 61223-3-4: min. diameter 2.0 mm at High speed mode, min. diameter 1.0 mm at High resolution mode	Low contrast resolution on IEC 61223-3-4: min. diameter 2.0 mm
	Cephalometric - spatial resolution	Line pair resolution on IEC 61223-3-4: min. 2.5 LP/mm	Line pair resolution on IEC 61223-3-4: min. 2.5 LP/mm
	Cephalometric - noise	Low contrast resolution on IEC 61223-3-4: min. diameter 2.5 mm	Low contrast resolution on IEC 61223-3-4: min. diameter 2.5 mm
	CBCT - spatial resolution	min. 10% MTF at 2.0 LP/mm at standard mode min. 10% MTF at 2.5 LP/mm at high resolution mode	min. 10% MTF at 2.0 LP/mm
	CBCT - noise	The standard deviation of the gray scale of the center region of the Contrast phantom shall be less than 12.5 (10% of the full scale).	The standard deviation of the gray scale of the center region of the Contrast phantom shall be less than 12.5 (10% of the full scale).

807.92(b)(l): Non-clinical Testing

The Veraview X800 has been tested for compliance and developed in accordance with the following international standards:

IEC/ISO Standard	FDA Recognition number
IEC 60601-1:2005+A.MD1:2012	19-4
IEC 60601-1-2:2007	19-1
IEC 60601-1-3:2008+AMD1: 2013	12-269
IEC 60601-1-6:2010+AMD1:2013	5-89
IEC 60601-2-54:2009+AMD1:2015	12-296
IEC 60601-2-63:2012	12-251
IEC 61223-3-4:2000	12-224
IEC 62304:2006+AMD1:2015	13-79
IEC 62366:2007+AMD1:2014	5-87
ISO 10993-1:2009/Cor1:2010	2-220
ISO 14971:2007	5-40

In addition to conformance with the above standards, non-clinical testing was conducted on the new device including imaging performance for all three modes of operation (panoramic, cephalometric, and CBCT).

807.92(b)(2): Clinical Testing

There were no clinical tests performed for Veraview X800.

807.92(b)(3): Conclusions from Testing

Based on the comparison of the Veraview X800 to the primary and reference predicates identified above and based on the non-clinical testing described above, it is concluded that the Veraview X800 is substantially equivalent to the primary predicate device.

The Veraview X800 device has the same intended use as the predicate device, and also offers the same imaging modalities as the predicate device (panoramic, cephalometric, and CBCT). Non-clinical testing demonstrates that the device performs in a substantially equivalent manner to the predicate device with regard to imaging and dose performance. Finally, the safety and overall performance of the device are demonstrated via conformance to the above stated applicable standards.