J. Morita USA, Inc.
℅ Mr. Keith Barritt
Attorney
Fish & Richardson P.C.
1000 Maine Avenue, S.W., Suite 1000
WASHINGTON DC 20024

February 18, 2021

Re: K201378
Trade/Device Name: 3D Accuitomo 150N Model X800N
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS, MUH
Dated: December 30, 2020
Received: December 31, 2020

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K201378

Device Name
3D Accuitomo 150N Model X800N

Indications for Use *(Describe)*

The 3D Accuitomo 150N Model X800N is intended to be used for panoramic tomography including linear tomography and scanogram, cephalometric radiography, and cone beam computed tomography.

The 3D Accuitomo 150N Model X800N 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 ENT, 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 medical doctors, 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.

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

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510(k) Summary K#201378
J. Morita USA Inc.
3D Accuitomo 150N Model X800N
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
Fax: 949-581-9688

(ii) 510(k) Submitter Contact

Keith A. Barritt
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1000 Maine Avenue, S.W., Suite 1000
Washington DC 20024, USA
Phone: (202) 626-6433
Fax: (202) 783-2331
Email: barritt@fr.com

(iii) Preparation Date

February 17, 2021

807.92(a)(2): Name of Device

Trade or Proprietary Name:	3D Accuitomo 150N Model X800N
Common Name:	Dental Computed Tomography X-ray System imaging
Device Classification Name:	System, X-Ray, Tomography, Computed
Review Panel:	892 Radiology device
Product Code:	OAS, MUH
Regulation:	21 CFR 892.1750 Class II
Device Class:	Traditional
510(k) Type:	

807.92(a)(3): Predicate Device

This device is substantially equivalent for purposes of FDA medical device regulations to the following predicate device:

Trade or Proprietary Name:	Veraview X800 (K#171012)
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

As discussed further below, the following J. Morita reference devices were used to confirm the suitability of the images of the 3D Accuitomo 150N Model X800N (the "X800N") for the general examination and diagnostic ENT indication being added: Veraviewepocs X550 (K#073696) and MCT-1 (K#073695).

807.92(a)(4): Device Description

The purpose of this 510(k) application is to obtain clearance from FDA for a new ENT indication for J. Morita's already cleared device, the Veraview X800 (K#171012). The new indication is for general examination and diagnosis of the skull including the ENT.

The X800N 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 X800N 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 X800N is:

- Panoramic tomography including linear tomography and scanogram
- Cephalometric radiography
- Cone beam computed tomography
- General examination and diagnosis of the skull including the ENT.

Indication for Use

X800N is intended to be used for panoramic tomography including linear tomography and scanogram, cephalometric radiography, and cone beam computed tomography. X800N 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 ENT, 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 medical doctors, dentists, and other legally qualified professionals for pediatric and adult patients.

807.92(a)(6): Technological Characteristics

The predicate device Veraview X800 (K#171012) is identical in regards to mechanical performance, imaging area, and the other safety and efficacy related parameters. For the X800N, exactly the same image as the dental application for the X800 is taken and utilized for the ENT application.

A comparison table of the X800N to the predicate device is shown below:

Item	Device submitted in this 510(k)	Predicate device
Product name	3D Accuitomo 150N	Veraview X800
Model	X800N	X800
Manufacturer	J. MORITA MFG. CORP.	Same as left
Indications for use	X800N is intended to be used for panoramic tomography including linear tomography and scanogram, cephalometric radiography, and cone beam computed tomography. X800N 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 ENT, 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-	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

Item		Device submitted in this 510(k)	Predicate device
		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 medical doctors, dentists, and other legally qualified professionals for pediatric and adult patients.	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.
Energy used and/or delivered		AC 120 V, 60 Hz	Same as left
Design	Loading factors	Tube Potential: 60-100kV Tube Current: 2-10mA Loading time: max. 18.5s	Same as left
	X-ray tube assembly	Nominal focal spot: 0.5 at target angle Inherent filtration min. 2.5mmAL	Same as left
	X-ray detector 1	Internal parts code: D001-15038-50* See column in predicate device.	Same as left
	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	Same as left

Item		Device submitted in this 510(k)	Predicate device
	X-ray detector 3	Internal parts code: D001-04188-50* See column in predicate device.	Same as left-
Soft-ware	Viewer (general purpose viewer: not included in this submission of the device)	Viewer software: 510K number: K073704 Device name: i-Dixel	Same as left
Perfor mance	Panoramic - spatial resolution	Line pair resolution on IEC 61223-3-4: min. 2.5 LP/mm	Same as left
	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	Same as left
	Cephalometric - spatial resolution	Line pair resolution on IEC 61223-3-4: min. 2.5 LP/mm	Same as left
	Cephalometric - noise	Low contrast resolution on IEC 61223-3-4: min. diameter 2.5 mm	Same as left
	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	Same as left
	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).	Same as left

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

The new X800N 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 60601-1-2:2014	19-8
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 60601-2-63:2017	12-310
IEC 61223-3-4:2000	12-221
IEC 62304:2006+AMD1:2015	13-79
IEC 62366:2015	5-114
ISO 10993-1:2009/Cor1:2010	2-220
ISO 14971:2007	5-40

The software changes were validated pursuant to the FDA's 2005 "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

807.92(b)(2): Clinical Testing

Clinical evaluation was performed to evaluate if the CT image obtained by the X800N for general examination and diagnosis of the ENT area is substantially equivalent to that obtained by J. Morita's reference devices, the X550 (K#073696) and MCT-1 (K#073695), which are FDA-authorized for "dental radiographic examination and diagnosis of teeth, jaw, oral structure, TM-joints and skull, including the ENT and dento-maxillofacial areas" and for taking x-ray images "of the head and neck areas, including the ENT and dento-maxillofacial areas, for use in diagnostic support," respectively.

Methods:

Experienced doctors who are using CBCT for their ENT medical practice subjectively evaluated images taken by the X800N, X550, and MCT-1.

The images they evaluated were obtained in J. Morita's facility from adult and child human skull phantoms made from resin molding on real human dry skulls. The use of phantom image for evaluation was judged to be appropriate in the majority of cases and no evaluator judged it is not suitable to use the phantom image.

The images were then ranked by the evaluators according to five categories: "Excellent Quality for Diagnosis," "Acceptable Quality for Diagnosis," Not Acceptable Quality for Diagnosis," "Not reviewed," and "Other."

Results:

All the evaluators ranked the images of the X800N as "Excellent Quality for Diagnosis" or "Acceptable Quality for Diagnosis." The overall results were better than that of the X550. Thus, the images of the X800N are comparable to the images from the X550. And the results of the X800N were comparable to the MCT-1.

807.92(b)(3): Conclusions from Testing

The clinical evaluation results show that the image quality of the X800N is comparable to the images quality of both the X550 and MCT-1. Thus, the images taken by X800N are sufficient to use for general examination and diagnosis of the ENT area.

As the only changes from the previous device are indication for use, change of display icon from dental figure, and the description of operation instructions for the ENT application, the X800N is substantially equivalent to the predicate device.