April 13, 2022

DentiMax, Inc.
% Mr. David Arnett
President
4115 E Valley Auto Dr, Suite 101
MESA AZ 85298

Re: K220556
Trade/Device Name: OpenSensorX Series
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: March 18, 2022
Received: March 23, 2022

Dear Mr. Arnett:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220556

Device Name
OpenSensorX Series

Indications for Use *(Describe)*
The OpenSensorX Series is used in conjunction with dental Radiography in medical units. The product is used for dental X-ray examination and the diagnosis of structural diseases. The product is expected to be used in hospitals and clinics, operated and used by trained professionals under the guidance of doctors. This device is not intended for mammography and conventional photography applications. This device is suitable for providing dental radiography imaging for both adult and pediatric.

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 OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

1. Date Prepared [21 CFR 807.92(a)(1)]

February 23, 2022

2. Submitter's Information [21 CFR 807.92(a)(1)]

Company Name:	DENTIMAX, INC.
Company Address:	4115 E. Valley Auto Drive, Suite 101 Mesa AZ 85206
Contact Person:	David J. Arnett
Phone:	(480) 396-1798
Email:	david@dentimax.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name:	OpenSensorX Series
Common Name:	Intraoral X-Ray Imaging System
Model Name:	OpenSensorX series
Classification Name:	Extraoral Source X-ray System
Product Code:	MUH
Regulation Number:	21 CFR 872.1800
Device Class:	II

4. Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]

The identification predicates within this submission are as follows:

Manufacturer:	DENTIMAX, INC.
Trade Name:	DentiMax Digital X-ray Imaging System
Model Name:	SENSORH1
	SENSORH2
Product Code:	MUH
Classification Name:	Extraoral Source X-ray System
FDA 510 (k) #:	K092547

5. Description of the Device [21 CFR 807.92(a)(4)]

OpenSensorX series are digital intra-oral sensors. It features a 20μm pixel pitch CMOS sensor with directly deposited CsI:Tl scintillator which ensures optimal resolution. An easy to use hi-speed direct USB interface enables a simple connection to a PC without need for an additional control box. The optional iRay intra-oral software application makes it easy to acquire, enhance, analyze, view and share images from the sensor.
The major function of the OpenSensorX series is to convert the X-ray to digital image, with the application of high resolution X-ray imaging. This detector is the key component of intra-oral DR system, enables to complete the digitalization of the medical X-ray imaging with the intra-oral DR system software.
The OpenSensorX series has two device models, OpenSensor0001X and OpenSensor0002X.

6. Intended Use [21 CFR 807.92(a)(5)]

6.1. Intended Use

The OpenSensorX Series is used in conjunction with dental Radiography in medical units. The product is used for dental X-ray examination and the diagnosis of structural diseases. The product is expected to be used in hospitals and clinics, operated and used by trained professionals under the guidance of doctors. This device is not intended for mammography and conventional photography applications. This device is suitable for providing dental radiography imaging for both adult and pediatric.

6.2. Suitable patient

This device is suitable for both adult and pediatric, but not suitable for pregnant women.

6.3. Processing of input and output

The sensor plate of OpenSensorX series are direct-deposited with CsI scintillator to achieve the conversion from X-ray to visible photon. The visible photons are transformed to electron signals by diode capacitor array within CMOS panel, which are composed and processed by connecting to scanning and readout

electronics, consequently to form a panel image by transmitting to PC through the user interface.

When OpenSensorX series work continuously, it can automatically distinguish X-ray and output an imaging for diagnosis of disease, injury, or of any applicable health problem.

7. Technological Characteristic [21 CFR 807.92(a)(6)]

Item	Predicate Device: DentiMax Digital X-Ray Imaging System	Proposed Device: OpenSensorX Series
510(K) Number	K092547	To be assigned
Classification Name	Extraoral Source X-ray System	Same
Product Code	MUH	Same
Regulation Number	21 CFR 872.1800	Same
Panel	Radiology	Same
Classification:	II	Same
X-Ray Absorber (Scintillator):	CsI	Same
Installation Type:	Portable	Same
Detector structure:	CCD and thin FOP(fiber optic plate)	CMOS Photodiode Array
Dimensions:	SENSORH1: 41mm×26.4mm×5.8mm SENSORH2: 42.3mm×30mm×5.8mm	OpenSensor0001X: 38.5mm×25mm×4.5mm OpenSensor0002X: 40mm×31mm×4.5mm
Image Matrix Size:	1500×1000 pixels for SENSORH1; 1700×1200 pixels for SENSORH2	1500×1000 pixels for OpenSensor0001X; 1800×1300 pixels for OpenSensor0002X
Pixel Pitch:	20μm	20μm
Effective Imaging Area:	30mm×20mm for SENSORH1; 34mm×24mm for SENSORH2	30mm×20mm for OpenSensor0001X; 35mm×26mm for OpenSensor0002X
Modulation Transfer Function (MTF)	0.1 at 7lp/mm	0.1 at 12.5lp/mm

Item	Predicate Device: DentiMax Digital X-Ray Imaging System	Proposed Device: OpenSensorX Series
Power Consumption:	DC +4.5 to 5.5V(480mA Max.)	5V DC, 400mA
Communications:	USB 2.0	Same
Protection against shock	Type BF applied part	Type BF applied part
Operation:	Temperature: 0 to 50℃ Humidity: 0 to 70% (Non-Condensing)	Temperature: 10 to 35℃ Humidity: 20 to 90% (Non-Condensing) Atmospheric pressure: 70 to 106 kPa Altitude: Max. 3000 meters
Storage and Transportation: （detector）	Temperature: -10 to 70℃ Humidity: 10 to 95% (Non-Condensing)	Temperature: -10 to 60℃ Humidity: 10 to 95% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters
Software	XRAY Vision Software(XVA3^{TM})	iRayDR

8. **System requirements to operate with other radiographic system components**

1) Recommended Generator Specification:

Energy range: 55~100kV

mA range: 10~1000mA (depending on the generator power)

ms range: 10~6300ms to produce 0.1~1000mAs (depending on the generator power)

Note: To our best knowledge, the OpenSensorX series are compatible with the X-ray generators with the specifications described above.

2) Application Program Interface (API) for system integration manufacturer

Peripheral hardware: OpenSensorX series connected via USB2.0 communication.

Operating System:	Windows 7 or above 32/64bit
CPU:	Intel Core i5 3.6G
Memory:	8G DDR3
Hard Disk:	640 G
USB port:	in accordance with USB2.0 interface

3) X-ray exposure mode

The AED mode can connect X-ray signal in the OpenSensorX series. Once there the X-ray generator exposure exist, the inner trigger module will detect the X-ray radiation and output signal to the intraoral sensor. Until the exposure is finished, the sensor will receive a signal which represents the end of exposure from the inner trigger module and begin to acquire the image.

9. Nonclinical study

1) Electrical Safety and EMC testing:

Electrical, mechanical, environmental safety and performance testing according to IEC/ES 60601-1 and IEC60601-2-65 were performed, and EMC testing was also conducted in accordance with IEC 60601-1-2. All test results meet the standard requirements.

2) Biological Evaluation:

Although there is a single-use protective sheeth prior to each use, the materials of the intra-oral sensor enclosure which may contact patient's oral mucosa have been evaluated with the ISO10993-1. And the evaluation results and test result assured the safety the same as the predicate device.

The sensor position frame is evaluate and assured the safety the same as the predicate device.

3) Nonclinical Considerations:

According to the *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices*, The non-clinical studies have been performed and the results have shown that the OpenSensorX series are substantially equivalent to the predicate devices on the Market (K092547):

Dose to output signal transfer function, Signal to noise ratio, uniformity, Defect, Minimum triggering dose rate, Modulation transfer function (MTF), Spatial resolution, Low contrast resolution and Image Acquisition time.

According to the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, the software iRayDR classifies the hazards, defines requirements specification and design specification, all the specification pass all the

test cases and complies the intended design specification.

4) Clinical Consideration:

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterizes all performance aspects of the device based on well-established scientific and engineering principles.

10. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Dentimax Inc. Concludes that OpenSensorX series are substantially equivalent to predicate device with regards to safety and effectiveness.