DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2017

Masterlink LLC
% Parul Chansoria
Regulatory Consultant
Elexes
6494 Tralee Village Drive
DUBLIN CA 94568

Re: K163282
Trade/Device Name: Apex Dental Sensors
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 6, 2017
Received: February 6, 2017

Dear Parul Chansoria:

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 contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

For

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 on last page.

510(k) Number *(if known)*

K163282

Device Name
Apex Dental Sensors

Indications for Use *(Describe)*
The Apex Dental Sensors is intended to be used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This 510(k) Summary has been created per the requirements of the Safe Medical Device Act (SMDA) of 1990, and the content is provided in conformance with 21 CFR Part 807.92.

Submitter's Information

Table 1 : Submitter's Information

Submitter's Name: Company: Address:	Tom Birney, CEO Masterlink, LLC. 24654 N. Lake Pleasant Parkway Suite 103-501 Peoria, AZ 85383
Contact Person:	Ms. Parul Chansoria Founder, Elexes
Phone:	650-528-2445
Fax:	---------
Email:	parul@elexes.com
Date of Summary Preparation:	11-11-2016

Device Information

Table 2 : Device Information

Trade Name:	Apex Dental Sensors
Common Name:	Intraoral Digital x-ray Sensors
Classification Name:	Extraoral source x-ray system
Classification Number:	Class II per 21 CFR 872.1800
Product Code:	MUH
Classification Panel:	Dental

Predicate Device Information

QuickRay HD Intraoral Sensor (K151926)

Device Description

The Apex Dental Sensors is an electronic medical device used to acquire intra-oral radiographic images. The sensor can be operated by Radiologists, Dentists, Dental Assistants and other healthcare professionals, who are both trained and competent to take Dental X-ray radiographs. Intra-oral

positioning of the sensor is accomplished by the use of dedicated intra-oral positioning devices that facilitate the accurate alignment of the x-ray beam. The sensor may also be aligned with the assistance of the patient. The Apex Dental Sensors is an indirect light converting digital x-ray detector. A scintillating device composed of Cesium Iodide (CsI) converts incident x-rays into visible light that is optically coupled to a light detection imager based on CMOS technology. The Apex Dental Sensors allow for automatic detection of such incident x-rays in order to generate data. Software interprets this data into images used for dental applications. The Apex Dental Sensors support USB 2.0 direct connectivity to personal computers and or laptops with dedicated electronics and a sensor software driver. The subject device does not control the generator, it is only a receiver. The X-ray system and the software used are not a part of this submission.

The following are the types of x-ray systems that would integrate with the Apex Dental Sensors.

MFR.	Model	Kv/mA	Adult		Child	
			Anterior	**Posterior**	**Anterior**	**Posterior**
Progeny	Preva	65*/*7	.080-.125	.125-.200	.040-.064	.064-.100
Sirona	Heliodent Plus	70*/7	.06-.10	.10-.16	.04-.06	.04-.08
Sirona	Heliodent DS	60/7	.80-.12	.12-.20	.04-.06	.04-.10
Gendex	765DC/Expert DC	65/7	.080-.125	.125-.200	.040-.063	.040-.100
Gendex	770	70/7	6-7 Pulses	7-10 Pulses	4-5 Pulses	5-7 Pulses
PlanMeca	Intra	66*/8*	.080-.120	.120-.200	.040-.080	.040-.100
Belmont	Belray	70/7*	.06-.10	.10-.16	.04-.06	.04-.08
Aribex	Normad (Handheld)	60/2.5	.34-.40	.40-.50	.25-.30	.30-.36

* Adjustable

The following hardware and software requirements need to be taken into account to ensure successful integration of Apex Dental Sensors with the X-ray systems.

Hardware requirements:

The type of x-ray systems that integrate with the Apex Dental Sensors are wall-mounted x-ray generators (both AC and DC) with a tube current between 1 and 15 mA inclusive, and with a tube voltage between 50 and 100 kV inclusive, with in-built controls to set exposure parameters. Generators allow variable mA/kV to be selected, all will control the exposure time.

The subject device is only a receiver, and not a controller. The subject device and the software cannot act as the controller of an x-ray generator. X-ray generators are controlled by built-in controllers.

Software requirements:

The Apteryx XrayVision software needs assistance from a TWAIN driver to recognise X-ray images. The recommended requirements for PC hardware for the sensor and software combination would be:

- Processor: Intel 1.2GHz chip or above
- Memory: Above 1G
- Hard disk: Above 40G

- Interface: USB 2.0
- Display: Resolution 1024 × 758 (15") or above
- Operating System: Windows XP
- The computer connected to system shall be in accordance with IEC 60950-1:2005

Indications for Use

The Apex Dental Sensors is intended to be used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.

Technological Characteristics

The Apex Dental Sensors (Subject Device) makes use of a Predicate Device, QuickRay HD Intraoral Sensor (K151926). The detectors in Apex Dental Sensors are the same as the detectors in the predicate device.The subject device and the predicate device are identical and sourced from the same supplier Hamamatsu. The model numbers of the Apex dental sensors are:

- **S11684-12 is Size #1**
- **S11685-12 is Size #2**

Table 3: Substantial Equivalence Table for Apex Dental Sensors			
Parameter	**Proposed Device (Subject Device) Apex Dental Sensors**	**QuickRay HD Intraoral Sensor (Predicate Device) K151926**	**Equivalence**
General			
Manufacturer	Masterlink LLC	Denterprise International, Inc.	
Intended Use	Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure	Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure	Equivalent
Indication for Use	The Apex Dental Sensors is intended to be used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.	QuickRay HD is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures	Equivalent
Class	II	II	Equivalent
Common Name	Intraoral Digital x-ray Sensor	Intraoral Digital x-ray sensor	Equivalent

Table 3: Substantial Equivalence Table for Apex Dental Sensors			
Parameter	**Proposed Device (Subject Device) Apex Dental Sensors**	**QuickRay HD Intraoral Sensor (Predicate Device) K151926**	**Equivalence**
Product Code	MUH	MUH	Equivalent
Classification Panel	Dental	Dental	Equivalent
Regulation Number	21 CFR 872.1800	21 CFR 872.1800	Equivalent
Classification Name	Extraoral source x-ray System	Extraoral source x-ray system	Equivalent
Key Features			
Number of Sensors	2	2	Equivalent
Cable Length	2m	2m	Equivalent
Pixel Size	20 x 20μm	20 x 20μm	Equivalent
Resolution	20 Lp/mm typ (S11684-12)	>= 20 Lp/mm	Equivalent
Technology	CMOS chip +optical fiber plate + CsI scintillator	CMOS chip +optical fiber plate + CsI scintillator	Equivalent
Matrix dimensions (mm^2)	Sensor Active Area: 600mm^2 (Size 1) 884mm^2 (Size 2)	Sensor Active Area: 600mm^2 (Size 1) 884mm^2 (Size 2)	Equivalent
Principles of Operation	X-ray (radiation) => scintillator (convert to light) => fiber optic (filtering) => CMOS (convert to digital)=> electronics=> PC (capture & display image)	X-ray (radiation) => scintillator (convert to light) => fiber optic (filtering) => CMOS (convert to digital)=> electronics=> PC (capture & display image)	Equivalent
Other Requirements			
Recommended PC Requirements	Processor: Intel 1.2GHz chip or above; Memory: Above 1G ; Hard disk: Above 40G; Interface: USB 2.0; Display: Resolution 1024 × 758 (15") or above Operating System: Windows XP The computer connected to system shall be in accordance with IEC 60950-1:2005.	Pentium 4 or better processor. At least 1 GB RAM, 200MB of hard drive space for the software, plus additional space for the user database (recommended 40GB minimum), USB 2.0 or 3.0 and 100MB wired Ethernet connection is needed if networked.	Equivalent

Table 3: Substantial Equivalence Table for Apex Dental Sensors			
Parameter	**Proposed Device (Subject Device) Apex Dental Sensors**	**QuickRay HD Intraoral Sensor (Predicate Device) K151926**	**Equivalence**
Connection to Imaging Practice PC	USB 2.0 Interface	USB 2.0 High-Speed	Equivalent
Software-Image Management	Apteryx XrayVision	Apteryx XrayVision	Equivalent
Sensor Board	All control electronics directly integrated on CMOS sensor chip	All control electronics directly integrated on CMOS sensor chip	Equivalent
Sensor input voltage and current	USB2.0 (5V, 4.25min)	5V (via USB connection); 0.15A Max	Equivalent
Operating Temperature	0℃～+35℃	0 °C to 35 °C	Equivalent
Electrical Safety			
Standards of Conformity	IEC 60601-1-1 (Electrical) IEC 60601-1-2 (EMC) 62220-1 (Performance) IEC 61326-1 (EMC) IEC 60601-2-65 (Electrical)	IEC 60601-1 (Electrical); IEC 60601-1-2 (EMC) 62220-1 (Performance) 60529 (IP Code)	Equivalent

Similarities

- The Apex Dental Sensors and Predicate Device both are available in two sizes
- The interface to PC of both Apex Dental Sensors and the Predicate is USB
- Both Apex Dental Sensors and the Predicate Sensor use CMOS technology, the pixel size for both sensors is 20 x 20μm
- The Sensor Active Area for Apex Dental Sensors and Predicate Device is the same i.e., 600mm²

(Size 1) and 884mm² (Size 2)

- The principles of operation of Apex Dental Sensors and Predicate Device is the same, i.e., X-ray (radiation)=> scintillator (convert to light) => fiber optic (filtering) => CMOS (convert to digital)=> electronics=> PC (capture & display image)
- The Software-Image Management of Apex Dental Sensors and Predicate Device is the same, i.e., Apteryx XrayVision which has been cleared by the FDA under (K983111)
- Both Apex Dental Sensors and Predicate Device have all control electronics directly integrated on CMOS sensor chip
- The sensor input voltage is 5V in both Apex Dental Sensors and Predicate Device
- The operating temperature of Apex Dental Sensors and Predicate Device is also comparable, i.e., 0℃～+35℃
- The Apex Dental Sensors and the Predicate Device are tested per IEC 60601-1-1 and 60601-1-2 for Electrical Safety and Electromagnetic compatibility
- The recommended PC requirements in Apex Dental Sensors and the Predicate Device is also comparable. The processor that is recommended for Apex Dental Sensors is Intel 1.2GHz chip or above whereas the processor for the Predicate Device is Pentium 4 or better.
- The Apex Dental Sensors and the Predicate Device have the same sensor resolution.
- The Apex Dental Sensors and the Predicate have the same cable lengths. The sensor cable length in Apex Dental Sensors is 2m and in Predicate Device is also 2m.
- The interface for Apex Dental Sensors requires USB 2.0, and the Predicate Device also utilizes USB 2.0.

Performance Data

The following Performance testing has been performed on the Subject Device in accordance with appropriate FDA guidance documents and relevant standards, to support the determination of substantial equivalence. The test data showed that the Subject device is safe and effective for its intended use.

- The Subject Device was tested to conform to the electrical and safety requirements established in AAMI ES 60601-1:2005/(R) 2012 and the electromagnetic compatibility requirements in IEC 60601-1-2 – Edition 3-2007
- The Subject Device was also tested to conform to IEC 62220-1:2003 – Determination of the Detective Quantum Efficiency Detectors used in Radiographic Imaging
- The Subject Device is in compliance with IEC 60601-2-65:2012 – Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
- The Subject Device is also in compliance with FDA guidance document – Guidance for the submission of 510(k)s for Solid State X-ray Imaging Devices

Conclusion

The Apex Dental Sensors is substantially equivalent to the Predicate, and does not raise any new or different questions of safety or effectiveness. The subject and the predicate devices are identical, the only difference exists in the trade names (for marketing purposes).