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

Denterprise International, Inc.
% Mr. Claude Berthoin
Regulatory Executive, Owner
100 East Granada Blvd., Suite 219
ORMOND BEACH FL 32176

December 14, 2015

Re: K151926
Trade/Device Name: QuickRay HD Intraoral Sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: November 24, 2015
Received: November 30, 2015

Dear Mr. Berthoin:

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,

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)*

K151926

Device Name
QuickRay HD Intraoral Sensor

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

100 E. Granada Blvd. Suite 219 Ormond Beach, FL 32176 Ph: 386-672-0450 800-323-2690

510 (k) Summary

Submitter

Denterprise International, Inc.
100 East Granada Blvd., Suite 219
Ormond Beach, FL 32176

Phone: 386-672-045
Fax: 855-235-7902
Contact Person: Claude Berthoin
Date Prepared: July 10, 2015

Device Classification

Trade Name:	QuickRay HD
Common Name:	Intraoral Digital X-Ray Sensor
Regulation Number:	21 CFR 872.1800
Classification Name:	Extraoral Source X-Ray System
Product Code:	MUH
Submission Type:	510(k)
Regulatory Class:	2
Medical Specialty:	Dental

Predicate Device

The following predicate is a legally marketed, post-amendment device:

510(k) Number:	K133271
Clearance Date:	April 28, 2014
Actual Trade Name:	Opteo
Regulation & PC:	872.1800; MUH

Reference Device:
510(k) Number: K150823
Clearance Date: August 265, 2015

Actual Trade Name: EDLENi Intra-oral Sensor
Regulation & PC: 872.1800; MUH

K150823 was in review when the subject device was submitted in July. This device is identical to the subject device. The K150823 would have been used as the predicate had it been available.

Device Description

The subject QuickRay HD are intraoral digital x-ray systems comprised of two components: (1) an intraoral detector which connects to a PC via a USB port; and (2) an Image Mangement Software package.

The subject devices comes in two sizes: Size 1 is 600mm² and Size 2 is 884mm².

QuickRay HD, Size 1 is also known as factory code S11684-12; QuickRay HD, Size 2 is also known as factory code S116845-12.

Before Denterprise sells this device, our technicians discuss the hardware and software that the dentist has, to make sure that their systems are compatible with the QuickRay HD sensor. Denterprise offers technical support for this device to ensure proper operation and to answer any questions regarding the function of the device. A means to contact Denterprise is provided to all end users and in our user manual.

The type of x-ray systems that integrate with the QuickRay HD sensor 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.

This device and software cannot act as an x-ray generator controller. All control of x-ray generation is done by controls built into the generator itself. **There is no connection between the subject device and the x-ray generator. The subject device does not control the generator, it is a receiver.**

X-ray Vision, software by Apteryx (K983111) cleared on November 16, 1998, is supported on Windows SP, Vista, 7, 8, 8.1 and 10. Absolute minimum requirements for PC hardware for the sensor and software combination would be a Pentium 4 or better processor. At least 1 GB of RAM, 200MB of hard drive space for the software, plus additional space for the user database (recommended 40GB minimum), a USB 2.0 or 3.0 and a 100MB wired Ethernet connection is needed if networked.

The Xray Vision software by Apteryx is a Windows based image management database/software primarily used by dentists to acquire, enhance, store, communicate, print, recall and display digital images.

The firmware in the QuickRay HD has already been cleared. The exact same device as the subject is EDLENi Intra-Oral Sensor, K150823. We could not use this device as our predicate because it was in review and cleared August 26, 2015. Our subject device was submitted for review in July 10, 2015. The subject device is identical in firmware/hardware from Hamamatsu, and the software is identical from Apteryx. Hamamatsu is the main subcontractor of this device for Denterprise International, Inc.

The EDLENi device also has 2 sizes like our subject device. The subject device and the EDLENi device are identical in all aspects of the device. They will have different names only for marketing purposes. The subject and predicate device are similar and the differences do not change the safety and effectiveness of the subject device.

The latest publication of CR Clinicians the November newsletter reports that 70% of all the practices use dental sensors and only 16% use film. This newsletter may be reviewed in section 21 _Other.

Indications for Use

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.

Intended Use

Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure.

The QuickRay HD dental sensor is intended to replace film and to capture an intraoral x-ray image, when exposed to X-rays, for dental diagnostic purposes.

Comparison of Technological Characteristics with Predicate

The subject QuickRay HD and predicate Opteo are similar dental devices.

Both are comprised of the following two components…

- Intraoral Detector System… The subject device and predicate device includes an intraoral detector, flexible cord, and direct USB 2.0 plug, as described in subject QuickRay HD and predicate Opteo marketing literature in this petition

- Imaging Software… The subject is using a third party software called Xray Vision which is manufactured by Apteryx in Akron, Ohio (K983111) cleared November 16, 1998. The predicate uses Owandy proprietary software called QuickView.

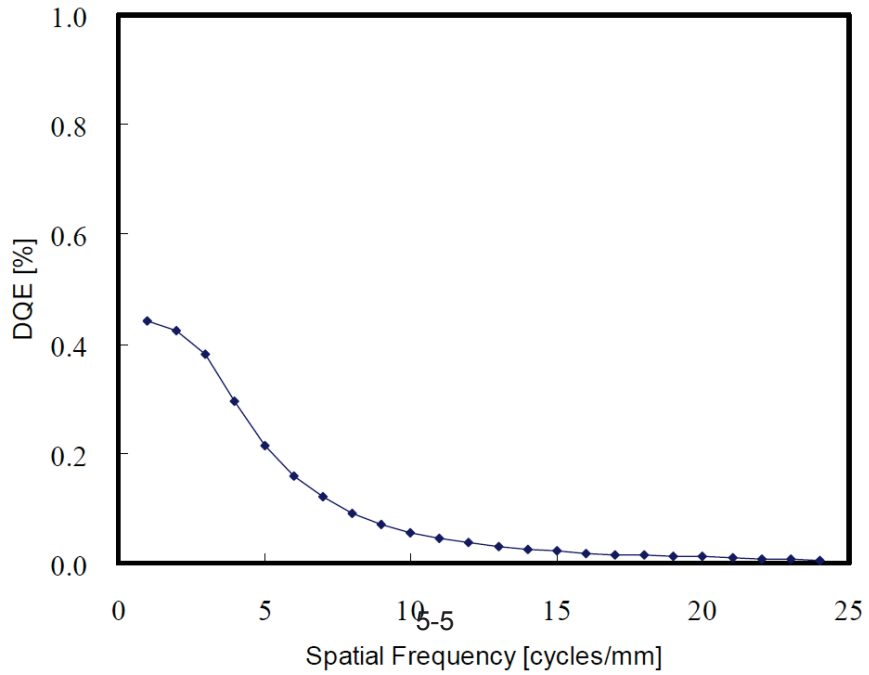
Comparison Table

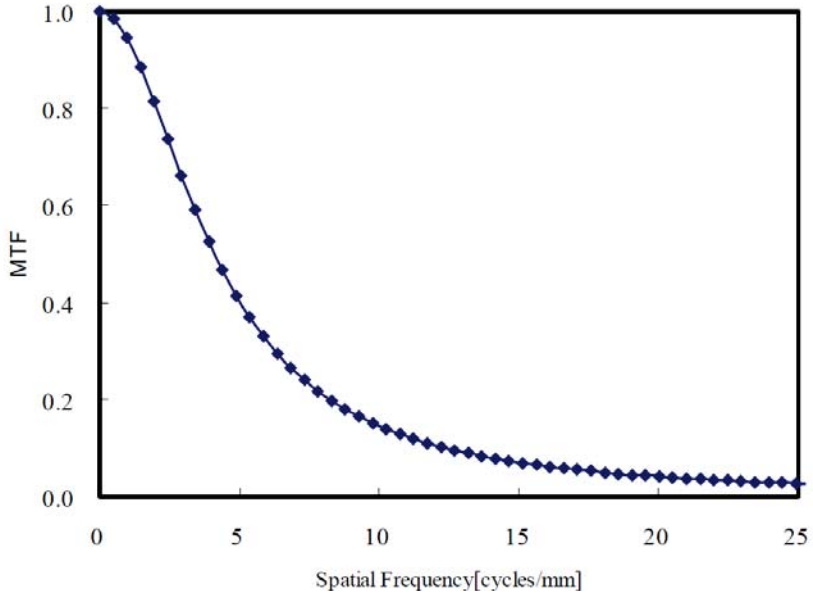
	QuickRay HD (Subject)	Opteo (Predicate)	Differences
510(k)	Not assigned yet	K133271 (Cleared April 28, 2014)	NA
Applicant/Assembler/ Repackager/Relabeler	Denterprise International (Ormond Beach, FL)	Owandy (Croissy-Beauvourg, France	NA
Manufacturer—Imaging SW Component	Apteryx (Akron, OH)	Owandy, France	Similar
Classification & Product Code	872.1800; MUH	872.1800; MUH	None
Common name	Intraoral Digital X-Ray Sensor	Intraoral Digital X-Ray Sensor	None
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.	None
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)	None
Software—Firmware	Firmware combined on sensor electronic board	Firmware combined on sensor electronic board	None
Software—Image Management	Xray Vision (OTS package from Apteryx, USA)	Owandy proprietary (QuickView) third party	None
Sensor technology	QuickRay HD: CMOS chip + optical fiber plate + CSi scintillator	CMOS chip + optical fiber plate + CSi scintillator	None
Matrix dimensions (mm2)	Active area: 600mm² (Size 1) 884mm² (Size 2)	Active area: 600mm² (Size 1); 900mm² (Size 2)	None
Matrix dimensions (pixels)	1000 lines X 1500 columns (Size 1); 1300 X 1700 (Size 2).	1000 lines X 1500 columns (Size 1); 1300 X 1700 (Size 2).	None
Lifespan CMOS	Min. 100,000 cycles	Min. 100,000 cycles	None
Resolution	Real ≥ 20pl/mm	Real ≥ 20pl/mm	None
Pixel size	20 X 20µm	20 X 20µm	None

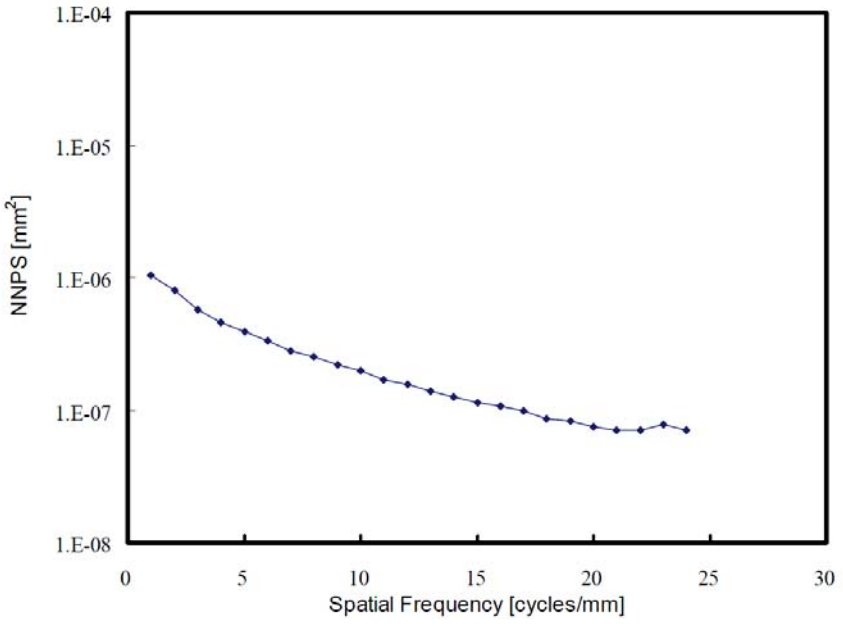
Grey levels	14 bits	14 bits	None
Sensor board	All control electronics directly integrated on CMOS sensor chip	All control electronics directly integrated on CMOS sensor chip	None
Sensor shell	Specific shape design; material is ABS and the flammability is HB if YK-94 (UL File No. 49895)	Specific shape design; material is thermoplastic polyamide (Grilamid LV3H Black)	None
Cable material and design	Cable consists of PVC, ETFE, copper, plug connector and sensor connector, diameter ϕ3.7 ±0.3 and cable length 2 meters.	4 conductor cable with polyurethane sheath, external global diameter of 3.5mm	None
Connection to imaging practice PC	USB 2.0 High-Speed	USB 2.0 High-Speed	None
Operating temperature	0°C to 35°C	10°C to 40°C	None
Sensor input voltage and current	5V (via USB connection); 0.15A Max	5V (via USB connection); 0.15A Max	None
Standards of conformity	IEC 60601-1 (Electrical); IEC 60601-1-2 (EMC) 62220-1 (Performance) 60529 (IP Code)	IEC 60601-1 (Electrical); IEC 60601-1-2 (EMC)	None

Input Calculation software*1 Output

$$DQE = \frac{MTF^2}{\Phi \cdot NNPS}$$




1.0
0.8
0.6
0.4
0.2
0.0
MTF
0
5
10
15
20
25
Spatial Frequency[cycles/mm]


1.E-04
1.E-05
1.E-06
1.E-07
1.E-08
NNPS [mm²]
0
5
10
15
20
25
30
Spatial Frequency [cycles/mm]

Performance Data

Clinical images were examined by Dr. Parham, a qualified practitioner in Ormond Beach, FL and found to be diagnostically relevant and reliable.

Biocompatibility

Biocompatible testing for the subject is not warranted because there are no direct or indirect patient-contacting components in the subject device. It is covered with a single-use protective barrier prior to each use just like the Opteo predicate.

Electrical Safety and EMC

EMC and electrical safety testing data reports for the subject device are provided in this petition.

- The QuickRay HD sensor conforms to electrical and safety standard IEC 60601-1 (Medical Electrical Equipment, Part I: General requirements for basic safety and essential performance).

- The QuickRay HD sensor conforms to electrical and safety standard IEC 60601-1-2 (Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential 3271performance – collateral standard: Electromagnetic compatibility).

Software Verification and Validation Testing

QuickRay HD electronics contains firmware along with a driver both provided by Hamamatsu. Additionally, QuickRay HD uses image management software provided by Apteryx Company; therefore, only firmware and driver documentation for the subject device are included in this petition.

Bench Testing

Bench tests were performed in conformance with IEC 62220-1 (Medical Electrical Equipment – Characteristics of Digital X-ray Imaging Devices—Part 1: Determination of the Detective Quantum Efficiency and IEC 60529 (Degrees of Protection Provided by Enclosures—IP Codes).

Conclusions

The subject and the predicate device have the same intended use and the same technological features. QuickRay HD and Opteo share the same principles of operation, sensor technology,

use the same USB connection to PC and use similar imaging firmware. The conclusion is that the subject device is as safe and effective as the predicate.

Since the subject device went in for review an identical device has been cleared. The EDLENi with K150823 was cleared August 26, 2015. This device is identical to the subject device. The sensors will only have different brand names for marketing purposes. Again, **K150823 and K151926 are identical**. Therefore, QuickRay HD warrants a finding of substantial equivalence to both the legally marketed original Opteo and the newly cleared EDLENi sensor and thus clearance for premarket activities in the United States.