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

Trident s.r.l.
% Mr. Claude Berthoin
President
Denterprise International, Inc.
100 East Granada Blvd., Suite 219
ORMOND BEACH FL 32174

November 4, 2016

Re: K162619
Trade/Device Name: I View and Imagen Sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: September 15, 2016
Received: September 20, 2016

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)*
K162619

Device Name
I View and Imagen Sensor

Indications for Use *(Describe)*
I-View dental sensor 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."

510k FDA Consulting

Medical Device Clearance

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

Traditional 510 (k) Summary

Submitter

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

Phone: 386-506-8711
Fax: 386-672-4402
Primary Contact: Joyce St. Germain, Regulatory Assistant (joyce@510kfda.com)
Secondary Contact: Claude Berthoin, President (claude@denterpriseintl.com)

Date Prepared: September 15, 2016

Device Classification

Trade Name: I View and Imagen Sensor
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: K151926
Clearance Date: December 14, 2015
Actual Trade Name: QuickRay HD
Regulation & PC: 872.1800; MUH

Reference Device:
510(k) Number: K150823
Clearance Date: August 26, 2015
Actual Trade Name: EDLENi Intra-oral Sensor
Regulation & PC: 872.1800; MUH

K151926 and K150823 are identical to the subject device. The devices are exactly the same except for the trade names being different for marketing purposes. All devices are made by Hamamatsu, Japan. <u>The only difference in the subject and predicate are the software packages; however their functionality is the same.</u> The subject device uses Deep-View and this software package has already been cleared with FDA in another device for Trident, K160386.

Device Description

The subject device I View is an 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.

The Size 1 sensor is also known as factory code S11684-12; Size 2 sensor is known as factory code S116845-12. I View and Imagen Sensor will both have Size 1 and Size 2. Two different trade names are for marketing purposes.

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

The type of x-ray systems that integrate with the I-View 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.**

The DEEP-VIEW software, is supported on Windows XP, Vista, 7,8,8.1. Absolute minimum requirements for PC hardware for the sensor and software and combination would be a Pentium 4 or better processor. At least 1 GB of RAM (2 GB optimal), 200MB of hard

drive space for the software, plus additional space for the user database (recommended 80GB minimum), a USB 2.0 or 3.0 and a 100MB wired Ethernet connection is needed if networked.

Images are captured by the sensor and transmitted in digital form via USB connection for display, storage and printing on the computer using ARCHIMED SUITE image capturing and management software. This software is brand labeled for Trident, known as DEEP_VIEW and has the same functionality as the software of the predicate device. ARCHIMED SUITE complies with the European Directive 93 / 42 EEC and CE Certification 1575/MMD issued by IMQ 0051 Italy.

The subject device is identical to the predicate and reference predicate in firmware/hardware from Hamamatsu. The predicate device QuickRay HD is cleared with K151926 and reference predicate, EDLENi cleared with K150823. Hamamatsu is the main subcontractor for all of these sensors. The devices are identical in firmware from Hamamatsu and having the same model number. The software is different; however, provides the same technology and intended use. The subject and predicate devices and the software difference does 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. This show the increase of dental sensors and that FDA has cleared these devices which shows the safety and effectiveness.

Indications for Use

I-View dental sensor 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 I-View is a dental sensor 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 device I View and predicate QuickRay HD <u>are the exact same dental devices.</u>

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 I View and predicate QuickRay HD and marketing literature is in this petition.

- Imaging Software… The subject device is using "DEEP-VIEW" that is a brand name for Trident of the software "Archimed Suite", a software produced by Digital Imaging. Archimed complies with the European Directive 93/42/EEC and subsequent amendments and additions (CE certification 1575/MMD issued by IMQ 0051, Italy). The predicate uses third party software called Xray Vision which is manufactured by Apteryx in Akron, Ohio (K983111) cleared November 16, 1998.

Comparison Table

	I-View Dental Sensor (Subject)	QuickRay HD Dental Sensor (Predicate)	Differences
510(k)	Not assigned yet	K151926 (Cleared December 14, 2015)	NA
Applicant/Assembler/ Repackager/Relabeler		Denterprise International (Ormond Beach, FL)	NA
Manufacturer—Imaging SW Component	DEEP-VIEW (Digital Imaging, Italy)	Xray Vision (Apteryx Akron, OH)	Similar
Classification & Product Code	872.1800; MUH	872.1800; MUH	None
Common name	Intraoral Digital X-Ray Sensor	Intraoral Digital X-Ray Sensor	None
Indications for Use	I-View dental sensor is 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 dental sensor is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.	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	DEEP-VIEW (package from Digital Imaging, Italy)	Xray Vision (package from Apteryx, USA)	None
Sensor technology	I View: CMOS chip + optical fiber plate + CSi scintillator	QuickRay HD: 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 ABS and the flammability is HB if YK-94 (UL File No. 49895)	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.	Cable consists of PVC, ETFE, copper, plug connector and sensor connector, diameter ϕ3.7 ±0.3 and cable length 2 meters.	None
Connection to imaging practice PC	USB 2.0 High-Speed	USB 2.0 High-Speed	None
Operating temperature	0°C to 35°C	0°C to 35°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) 60601-2-65	IEC 60601-1 (Electrical); IEC 60601-1-2 (EMC) 62220-1 (Performance) 60529 (IP Code)	One additional test for subject device

Performance Data

Clinical images were examined by Dr. Parham, a qualified practitioner in Ormond Beach, FL and found to be diagnostically relevant and reliable. These tests were provided for the predicate device submission because the subject device is identical to the predicate dental sensor, test reports for the I-View / Imagen sensor are not necessary to demonstrate device effectiveness.

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 QuickRay HD predicate.

Electrical Safety and EMC

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

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

I view and Imagaen Sensor electronics contains firmware along with a driver both provided by Hamamatsu. Additionally, I View and Imagen Sensor uses image management software provided by Digital Imaging, Italy; 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. I View and Imagen Sensor and QuickRay HD 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 as previously stated, these devices are identical in structure and use. The sensors will only have different brand names for marketing purposes. Again, **K150823 and K151926 are identical to the subject sensors I View and Imagen Sensor.** The software packages of the subject device and the predicate are different. The subject device software, Deep-View has been FDA cleared with other similar devices. Additional information regarding Deep-View is stated throughout the submission.

The I-View and Imagen Sensor warrants a finding of substantial equivalence to both the legally marketed original QuickRay HD and the EDLENi sensor and thus clearance for premarket activities in the United States.