Trident s.r.l
℅ Joyce St. Germain
Regulatory Consultant
The 510K Consulting, LLC
1449 Springleaf Drive
ORMOND BEACH FL 32174

April 15, 2020

Re: K200625
Trade/Device Name: I-View Gold and Imagen Gold Dental Sensors
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: March 5, 2020
Received: March 10, 2020

Dear Joyce St. Germain:

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)*
K200625

Device Name
I-View Gold and Imagen Gold Dental Sensors

Indications for Use *(Describe)*
I-View Gold sensors are digital dental intraoral sensors intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.

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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The 510k Consulting, LLC
1449 Springleaf Dr., Ormond Beach, FL 32174
Key to success in obtaining your medical device clearance
Joyce510kfda@gmail.com

510(k) Summary

Submitter/Applicant

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Consultant/Contact

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Contact: Joyce St. Germain, Regulatory Consultant, joyce510kfda@gmail.com

Device Classification

Trade/Model Names: I-View Gold and Imagen Gold Dental Sensors
Common Name: Intraoral Digital X-ray Dental Sensors
Classification Name: System, X-ray, Extraoral Source, Digital
Regulation Name: Extraoral Source X-ray System
Regulation Number: 21 CFR 872.1800
Product Code: MUH
Regulatory Class: II
510k Review Panel: Radiology

Predicate Device

The subject device claims equivalence to the following legally marketed predicate:

510(k) Number: K153060
Date Cleared: November 10, 2015
Trade Name: EzSensor Classic; HDI-U10DB and HDI-U20DB

Common Name:	Intraoral Digital X-ray Dental Sensors
Classification Name:	System, X-ray, Extraoral Source, Digital
Regulation Name:	Extraoral Source X-ray System
Regulation Number:	21 CFR 872.1800
Product Code:	MUH
Regulatory Class:	II
510k Review Panel:	Radiology

The predicate device, K153060, is the identical sensor as the subject and manufactured by Rayence. The devices for this submission have different trade names and different software brand names. The difference in the subject and predicate devices are the software packages; however, their functionality is the same.

Indications for Use

I-View Gold sensors are digital dental intra oral sensors intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.

Intended Use

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

Device Description

The subject I-View Gold and Imagen Gold sensors 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 Management Software package.

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

Direct digital systems acquire images with a sensor that is connected to a computer to produce an image almost instantaneously following exposure.

The primary advantage of direct sensor systems is the speed with which images are acquired.

For patient comfort, the ergonomic design is based on human intraoral anatomy.

- Excellent image quality based on advanced CMOS technology
- More comfortable sensor ergonomic shape for the human oral structure
- Lower dose exposure (Compared to film sensor)
- Enhanced durability
- Easy-to-use USB interface

The I-View Gold and Imagen Gold sensors have reference numbers as follows:

I-View Gold – size 1 Ref # ISO14-S

I-View Gold – size 2 Ref # ISO15-S

Imagen – size 1 Ref # ISO 18-S

Imagen – size 2 Ref # ISO19-S

NOTE: 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 these sensors. Trident offers technical support for these devices to ensure proper operation and to answer any questions regarding the function of the devices. 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 Gold and Imagen sensors are wall-mounted 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.**

Archimed Suite is a software produced by Digital Imaging and Deep-View is a brand name for Trident. Archimed Suite / Deep-View software was cleared with K160386 and K162619.

I-View Gold sensors use DEEP-VIEW software that is connected by a 'USB A' cable to a compatible Windows XP or Windows Vista or Windows 7 PC. I-VIEW GOLD is provided the power from PC. Support for the I-VIEW GOLD is provided by compatible software programs such as Deep-View.

DEEP-VIEW and ARCHIMED SUITE complies with the European Directive 93/42 EEC (and its revised version) and CE Certification issued by IMQ 0051, Italy.

The subject device is intended to be used by dentists, radiologists and other legally qualified professionals.

Comparison of Technological Characteristics with Predicate

The following table compares technological and other characteristics of the subject and predicate device.

Table 5 -- Technological Comparison

	Subject Device **I-View Gold, Imagen Gold**	**Predicate Device** **EzSensors (Detailed list on page 1 of this document)**	
510(k)	Not assigned yet	K153060 (Cleared November 10, 2015)	NA
Applicant	Trident s.r.l., Italy	Rayence, Korea	NA
Manufacturer— Imaging Software Component	Deep-View brand name of Archimed Suite produced by Digital Imaging	Easy Dent/EzDent-I by Rayence	Difference
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 Gold (and Imagen Gold) sensors are digital dental intra oral sensors intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for	Digital Dental Intra Oral Sensor is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.	None

	diagnostic use by dentists.		
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
Sensor Dimensions (mm)	Size 1.0: 36.8 x 25.4 Size 2.0: 42.9 x 31.3	Size 1.0: 36.8 x 25.4 Size 1.5: 39.5 x 29.2 Size 2.0: 42.9 x 31.3	Difference (Predicate has an additional size sensor)
Sensor Thickness (mm)	4.8	4.8	None
Active Area (mm)	Size 1.0: 30.01 x 20.01 Size 2.0: 35.99 x 25.99	Size 1.0: 30.01 x 20.01 Size 1.5: 33.00 x 23.98 Size 2.0: 35.99 x 25.99	Difference (Predicate has an additional size sensor)
USB Module	Integrated USB 2.0 module	Integrated USB 2.0 module	None
Pixel Pitch Full resolution / Binning mode	14.8 / 29.6	14.8 / 29.6	None
DQE (6lp/mm) Full resolution / Binning mode	0.38 / 0.34	0.38 / 0.34	None

MTF (3lp/mm) Full resolution / Binning mode	0.642 / 0.630	0.642 / 0.630	None
Typical dose range	Incisor & Canine: 300 ~ 500 / Molar: 400 ~ 600	Incisor & Canine: 300 ~ 500 / Molar: 400 ~ 600	None
Standards of Conformity	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 62336 EN 62304 IEC 60529 ISO 15223-1 ISO 14971	IEC 60601-1 IEC 60601-1-2	**Both devices passed standards performed**

Guidance Documents

This petition was prepared in conformance with the following FDA guidance instructions and documents:

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014

Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff Document issued on November 28, 2017.

Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff Document issued on: September 1, 2016

Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11, 2005 Medical Devices, Document issued on: May 11, 2005

Non-Clinical Performance Data

The following performance data were provided in support of the substantial equivalence determination.

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 Rayence predicate device.

Electrical Safety and EMC… The device does require EMC and Electrical Safety evaluation. EMC and electrical safety testing data reports for the subject device are provided in this petition.

• The I View and Imagen Sensors 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 3271 performance – collateral standard: Electromagnetic compatibility).

Software … The device does contain software/firmware. I-View Gold and Imagen Sensor electronics contains firmware along with a driver and both use image management software provided by Digital Imaging, Italy; therefore, only firmware and driver documentation for the subject device are included in this petition.

Performance Testing… Bench tests were performed and the SSIX Report is shown in this submission. Additional certificates for the device are also within this submission.

Conclusion

The subject and the predicate device have the same intended use and the same technological features. I View Gold and Imagen Gold Sensors and 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 Gold and Imagen Gold 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 Gold and Imagen Gold Sensors** warrants a finding of substantial equivalence to both the legally marketed EzSensor Classic Series and thus clearance for premarket activities in the United States.