July 5, 2024

Zinnovi Inc.
℅ Abdel Halim
President & MRP
Global Quality and Regulatory Services
10 Scenic Way
MONROE, NJ 08831

Re: K241649
Trade/Device Name: DUO1 and DUO2
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: June 7, 2024
Received: June 7, 2024

Dear Abdel Halim:

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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241649

Device Name
DUO1 and DUO2

Indications for Use *(Describe)*
The DUO Sensors are USB driven intraoral sensors which are intended to acquire intraoral radiographic images. The DUO Sensors shall be operated by trained healthcare professionals, who are educated and competent to perform the acquisition of intraoral radiographs.
The DUO Sensors can be used either in combination with special positioning devices to facilitate positioning and alignment with the X-ray beam or they may also be positioned by hand with the assistance of the patient.

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

Date Prepared:

June 14th, 2024

Manufacturer and 510(k) Owner:

Name : Zinnovi, Inc.

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Official Contact: Swaroop Patel (CEO and Co-founder)

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Representative/Consultant:

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Company : Qualomics LLC

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Telephone: +1 (858) 247-6804

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Identification of New Device

Owner/Operator:	Zinnovi Inc.
Premarket Notification Number:	K241649
Trade Name:	DUO1 and DUO2
Common Name:	Dental digital X-ray sensor
Classification Name:	Extraoral Source X-ray System
Product Code:	MUH
Submission Type:	510(k)
Classification:	Class II
Panel/Medical Specialty:	Radiology/Dental
Regulation Number:	21 CFR 872.1800
Manufacturer:	Zinnovi Inc.

Identification of Predicate Device

Owner/Operator:	RealCloud Imaging Inc. doing business as RealCloud Imaging
510(k) Premarket Notification Number:	K221955
Trade Name:	Brasseler GEM

Common Name:	Dental digital X-ray sensor
Classification Name:	Extraoral Source X-ray system
Product Code:	MUH
Classification:	Class II
Panel/Medical Specialty:	Radiology/Dental
Regulation Number:	21 CFR 872.1800
Manufacturer:	RealCloud Imaging Inc. doing business as RealCloud Imaging

Device Description

The DUO sensors are USB-driven digital X-ray sensors designed for health care professionals who are already acquainted with the standard procedures for acquiring dental intraoral radiographs. Digital X-ray imaging is an aide for diagnosis and should always be confirmed by the doctor using appropriate additional diagnostic aides, professional judgment, and experience.

The DUO Sensors are indirect converting X-ray detectors. A scintillating material converts the incident X-rays into visible light, this light is coupled optically to a CMOS technology light detection imager, and then converted to digital data.

The design of the sensor assembly supports the automatic detection of incident X-rays to generate digital images for intraoral applications, once armed via a software command. The digital image created is immediately visible on the screen of a personal computer connected to the DUO sensor through the standard USB port. For DUO sensors to be used in a dental practice, an optional image analysis software will be necessary. Image analysis software is not part of the submission. DUO captured X-ray images are suitable for recognition of normal anatomical structures, dental pathologies, and abnormal conditions.

The DUO sensors support USB2.0 connectivity to computers using a dedicated electronic assembly and a sensor software driver. Functions of the DUO sensors are controlled by software. Software drivers and utilities support sensor activation and settings.

The DUO sensors are manufactured with the same device firmware as the predicate device, Brasseler GEM.

Indications for Use

The DUO Sensors are USB driven intraoral sensors which are intended to acquire intraoral radiographic images. The DUO Sensors shall be operated by trained healthcare professionals, who are educated and competent to perform the acquisition of intraoral radiographs.

The DUO Sensors can be used either in combination with special positioning devices to facilitate positioning and alignment with the X-ray beam or they may also be positioned by hand with the assistance of the patient.

Intended Use

The DUO sensors are intended for any dental practice that uses X-ray equipment for intraoral diagnostic purposes. DUO sensors can be used by trained dental professionals for patients receiving intraoral X-ray examinations and procedures for capturing digital X-ray images. Captured digital X-ray images can be used for examinations and diagnostic purposes with the help of optional image analysis software. The optional image analysis software is not part of this submission. DUO sensors can be used with dental positioning devices and holders to assist with aligning an X-ray source beam with the sensor and anatomy.

Comparison Table

The following comparison table compares Zinnovi DUO to the predicate device, Brasseler GEM, with respect to intended use, indications of use, environment of use, limitations of use, technical performance, and technological characteristics, and provides more detailed information regarding the basis for the determination of substantial equivalence.

Comparison Table

Descriptive Information	Zinnovi DUO	Brasseler GEM	VERDICT
510(k) Number	K241649	K221955	NA
Manufacturer	Zinnovi Inc.	RealCloud Imaging Inc. doing business as RealCloud Imaging	NA
Trade Name	DUO1 DUO2	Brasseler GEM10 Brasseler GEM15 Brasseler GEM20	NA
Classification Name	Digital X-ray Sensor	Digital X-ray Sensor	Same
Classification	Class II	Class II	Same
Classification Panel/ Medical Specialty	Radiology/Dental	Radiology/Dental	Same
Regulation Number	21 C.F.R. §872.1800	21 C.F.R. §872.1800	Same
Product Code	MUH	MUH	Same
Number of Sensors	2	3	Different

Sensor Exterior Sizes	36.36 mm x 24.53.mm 41.80 mm x 30.48 mm	36.36 mm x 24.53.mm 38.83 mm x 29.63 mm 41.80 mm x 30.48 mm	Same NA Same
Sensor Imaging Sizes	30.26 mm x 20.32 mm 36.08 mm x 26.25 mm All with four clipped corners	30.26 mm x 20.32 mm 33.15 mm x 26.25 mm 36.08 mm x 26.25 mm All with four clipped corners	Same NA Same Same
Overall Imaging Areas	615 mm2 947.1mm2	615 mm2 870 mm2 947.1mm2	Same NA Same
Pixel Size	19.5 µm	19.5 µm	Same
Image Resolution	1539 x 1026 pixels (1.70 M pixels) 1842 x 1324 pixels (2.40 M pixels)	1539 x 1026 pixels (1.70 M pixels) 1692 x 1324 pixels (2.2 M Pixels) 1842 x 1324 pixels (2.40 M pixels)	Same NA Same
X-Ray Resolution	20 visible lp/mm	20+ visible lp/mm	Different
Dynamic Range	16,384:1	16,384:1	Same
Technology	CMOS	CMOS	Same
Scintillator Technology	Cesium Iodide	Cesium Iodide	Same
Operating System	Microsoft Windows 10 and Windows 11	Microsoft Windows 7 and 10	Different
Extraoral source	X-ray system	X-ray system	Same
Interface to PC	USB 2.0, Type A	USB 2.0, Type A	Same
Cable Length	0.6m and 1.9m	1.9 m and 2.9 m	Different

Power Consumption	0.8 Watts Max	0.8 Watts Max	Same
Electrical Rating	DC 5V, 350 mA max	DC 5V, 350 mA max	Same
Sterilization	Not suitable for sterilization	Not suitable for sterilization	Same
Housing	IPx8 Equivalent ISO 10993-1 Biocompatible	IPx8 Equivalent ISO 10993-1 Biocompatible	Same
Indications for use	The DUO Sensors are USB driven digital intraoral sensors which are intended to acquire intraoral radiographic images. The DUO Sensors shall be operated by trained healthcare professionals, who are educated and competent to perform the acquisition of intraoral radiographs. The DUO Sensors can be used either in combination with special positioning devices to facilitate positioning and alignment with the X-ray beam or they may also be positioned by hand with the assistance of the patient.	Brasseler GEM is a USB driven digital intraoral X-ray sensor which is intended to acquire dental radiographic images. Brasseler GEM must be operated by healthcare professionals who have been trained and are competent using various methods of acquiring radiographic images of dental anatomy. Brasseler GEM can be used with dental positioning devices and holders to assist with aligning an X-ray source beam with the sensor and anatomy. Brasseler GEM can also be aligned by hand with assistance of the patient.	Same
Intended Use	The DUO sensors are intended for any dental practice that uses X-ray equipment for intraoral diagnostic purposes. DUO sensors can be used by trained dental professionals for patients receiving intraoral X-ray examinations and procedures for capturing digital X-Ray images. Captured digital X-ray images can be used for examinations and diagnostic purposes with the	Brasseler GEM is intended for any dental practice that uses X-ray equipment for intraoral diagnostic purposes. Brasseler GEM can be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images for patients receiving intraoral X-ray examinations for diagnostic purposes. An image analysis software is	Same

	help of optional image analysis software. The optional image analysis software is not part of this submission. DUO sensors can be used with dental positioning devices and holders to assist with aligning an X-ray source beam with the sensor and anatomy.	not part of this submission. When Brasseler GEM is to be used in a dental practice, an optional software will be necessary. Brasseler GEM is a USB-driven digital intraoral X-ray sensor which is intended to acquire dental radiographic images. Brasseler GEM must be operated by healthcare professionals who have been trained and are competent using various methods of acquiring radiographic images of dental anatomy. Brasseler GEM can be used with dental positioning devices and holders to assist with aligning an X-ray source beam with the sensor and anatomy.	

Comparison of MTF of Zinnovi DUO and MTF of Brasseler GEM

Zinnovi DUO uses a sensor component from contract manufacturer BAE Systems Imaging Solutions, a division of BAE Systems Inc., which is also responsible for the manufacture of Brasseler GEM which is the predicate device. The components used in Zinnovi DUO are the exact same components used in predicate device Brasseler GEM. The sensor MTF versus spatial frequency for Zinnovi DUO and the sensor MTF versus spatial frequency for the predicate device, Brasseler GEM, are identical.

Comparison of DQE for Zinnovi DUO and DQE of Brasseler GEM

On behalf of Zinnovi Inc., BAE Systems Imaging Solutions has compared the DQE for Zinnovi DUO with the DQE of Brasseler GEM and has determined that they are substantially equivalent to each other.

Meaningful Differences

Zinnovi DUO and Brasseler GEM are CMOS X-ray image sensors. Zinnovi has compared the MTF and the DQE of DUO sensor to the MTF and the DQE of Brasseler GEM and has determined they are substantially equivalent to each other. DUO is not only similar in performance to Brasseler GEM but is also safe and effective based on performance testing.

Number of sensors: Zinnovi offers the smallest and largest sizes equivalent to the Brasseler GEM and would therefore be effective on the same patient population.

Operating System: Zinnovi offers device drivers to work with the latest Microsoft operating system.

X-Ray Resolution: DUO and predicate Brasseler GEM both have the same theoretical maximum resolution of 25 lp/mm.

Cable Length: Cable length has no effect on the performance of the product.

Sterilization

DUO sensors are not sold as sterile. Zinnovi Inc. recommends that usage of DUO sensor requires a hygienic barrier that meets ISO 10993 requirements for biocompatibility.

Biocompatibility

Biocompatibility testing is not needed with a rationale that considers all relevant endpoints because all materials and manufacturing/processing are identical to the predicate device, Brasseler GEM. The biocompatibility of DUO Sensors are based on the biocompatibility of the predicate device, Brasseler GEM. The DUO Sensor and the predicate Brasseler GEM are intended to be used in the oral cavity by a trained clinician.

SABIC Resin for Sensor Housing of DUO

BAE Systems Imaging Solutions uses the same SABIC resin for the sensor housing of DUO sensor that BAE Systems Imaging Solutions uses for the sensor housing of the predicate device, Brasseler GEM.

Software Information

The software for the DUO sensor consists of a simple API that can be provided to developers of existing FDA cleared image capture/dental imaging software to facilitate DUO sensor.

Risk Analysis

Zinnovi Inc. used a specified procedure for evaluating the safety of a device by identifying potential hazards and estimating the associated risks as required in the Software Design and Development Procedure subsection of the Software Information section. Zinnovi Inc. performed an extensive risk analysis of DUO sensor in accordance with the following reference standards: ISO 14971, IEC 60601-1; and IEC 60601-1-2: Medical Electrical Equipment, Part 1-2 to generate a risk analysis report.

Comparison of Safety and Effectiveness of DUO to Safety and Effectiveness of Brasseler GEM

Using the above Comparison Table, DUO sensor can be compared to the predicate device, Brasseler GEM, with respect to intended use, indications of use, environment of use, limitations of technical performance and technological characteristics and provides more detailed information regarding the basis for the

determination of substantial equivalence. There are no differences between DUO and Brasseler GEM with respect to indications and intended use.

Performance Testing-Bench

On behalf of Zinnovi Inc, Intertek performed extensive bench testing on DUO Sensor in accordance with the following reference standards: ANSI AMI ES 60601-1 Edition 3.2 2020-08; IEC 62304 Edition 1.1 2015-06; IEC 60601-1-2 Edition 4.0 2014-02.

The results of these tests indicate that the DUO Sensor is substantially equivalent to the predicate device.

Performance Testing-Clinical

Zinnovi performed a clinical performance testing to determine that DUO performed similar or better than the predicate device, Brasseler GEM. Zinnovi has provided clinical images captured with both the devices in a performance testing report which were evaluated by US dentists. These clinical images provide evidence in addition to the bench performance data that shows that the complete system works as intended.

Conclusion

On behalf of Zinnovi Inc., BAE Systems Imaging Solutions has compared DUO Sensor with the predicate device, Brasseler GEM, and has determined that they are substantially equivalent to each other in intended use, indications for use, safety and effectiveness, and technical characteristics.