August 31, 2022

RealCloud Imaging Inc. dba RealCloud Imaging
% Mr. W. Edward Johansen
Official Correspondent
W. Edward Johansen
1239 Stanford Street, Apartment Number 205
SANTA MONICA CA 90404

Re: K221955
Trade/Device Name: Brasseler GEM
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: July 1, 2022
Received: July 5, 2022

Dear Mr. Johansen:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221955

Device Name

Brasseler GEM

Indications for Use *(Describe)*

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 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary - K221955**

Submitted: July 27, 2022

**A. Corporation Information**

Name: RealCloud Imaging Inc.

Address: 2625 North Loop Drive, Suite 2130, Ames, Iowa 50010

Telephone:(712) 301-3882

E-mail address: doug.golay@realcloudimaging.com

Official Correspondent: W. Edward Johansen

Telephone: (310) 795-7425

E-mail address: wedjohansen@msn.com

Address: 1239 Stanford Street, #205, Santa Monica, California 90404

**B. Identification of New Device**

Owner/Operator: RealCloud Imaging Inc. doing business as RealCloud Imaging

Owner/Operator Number: 10052982

Establishment Registration Number: 3013464458

Trade Name: Brasseler GEM

Premarket Notification Number: K221955

Common Name: Dental digital x-ray sensor

Classification Name: Extra-oral source x-ray system

Product Code: MUH

Class: II

Panel/Medical Specialty: Radiology/Dental

Regulation Number: 21 C.F.R. §872.1800

Manufacturer: RealCloud Imaging

Contract Manufacturer: BAE Systems Imaging Solutions, a division of BAE Systems Inc.

Sterilization Facility: Not Applicable

## C. Identification of Predicate Device

Owner/Operator: SOTA Precision Optics, Inc. doing business as SOTA Imaging

Owner/Operator Number: 905754

Establishment Registration Number: 3000190675

510(k) Premarket Notification Number: K202664

Trade Name: Clio Prime

Common Name: Dental intraoral x-ray sensor

Classification Name: Extra-oral source x-ray system

Product Code: MUH

Classification: Class II

Panel/Medical Specialty: Radiology/Dental

Regulation Number: 21 C.F.R. §872.1800

Manufacturer: Sota Precision Optics, Inc. dba SOTA Imaging

Contract Manufacturer: BAE Systems Imaging Solutions, a division of BAE Systems Inc.

Sterilization Facility: Not Applicable

## D. Device Description

Brasseler GEM is a USB-driven digital sensor designed for health care professionals 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 judgement, and experience.

Brasseler GEM10 is for pediatric use and adult periapical use, GEM15 is for pediatric and adult bitewing and periapical use, and GEM20 is for adult use including bitewings. The Brasseler GEM design uses advanced ergonomic principles with four beveled corners, a moderate profile, and a rounded casing providing enhanced comfort for patients. Brasseler GEM is positioned in the patient's mouth in the same manner as intraoral film is positioned.

Brasseler GEM has a CMOS x-ray imager that creates a digital image from x-ray doses perceptible by the sensor. The digital image created is immediately visible on the screen of a personal computer connected to Brasseler GEM through the standard USB port. Image analysis software is not part of the submission. For Brasseler GEM to be used in a dental practice, an optional image analysis software will be necessary. Only with image analysis software can acquired images be optimized for specific diagnostic tasks, archived as image files, and printed out on a suitable printer. Software provides drivers and utilities for x-ray dose optimization, sensor activation and settings. Brasseler GEM capture x-ray images suitable for recognition of normal anatomical structures, dental pathologies, and abnormal conditions. Inadequate images may result in misdiagnosis thereby subjecting the patient to incorrect or unnecessary dental procedures that would present an unacceptable risk to the patient. Functions of the Brasseler GEM detector are controlled by software (firmware). The software of Brasseler GEM is of Moderate Level of Concern and is not based on the software of the predicate, Clio Prime.

Brasseler GEM shall be operated by healthcare professionals who are educated and competent to perform the acquisition of dental intraoral radiographs. Brasseler GEM can be used either in combination with positioners manufactured to facilitate the positioning and alignment with an x-ray beam, or it may also be positioned by hand with the assistance of the patient. Brasseler GEM can be used with patients of any age, providing the correct positioning of the sensor in the patient mouth can be realized. Using Brasseler GEM is a suitable diagnostic method and may offer reduced radiation exposure compared to analog procedures. Available software image enhancement tools may enhance sensitivity and consequently reduce errors introduced by subjective analysis. Brasseler GEM can perform and achieve the same type of two-dimensional images as conventional (traditional) film sizes 0, 1 and 2. Brasseler GEM cannot be used to, or as a substitution for extraoral or other types of dental x-ray. When using Brasseler GEM and software as a diagnostic aide, clinical experience and a combination of the diagnostic aides should be used to form a diagnosis and should not be solely relied upon for diagnosis.

## E. Indications for Use

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 patient.

### F. Intended Use

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 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.

## G. Performance Testing-Animal

RealCloud Imaging did not perform animal performance testing.

### H. Performance Testing-Bench

On behalf of RealCloud Imaging Intertek performed extensive bench testing on Brasseler GEM in accordance with the following reference standards: ANSI AMI ES 60601-1; IEC 62304; IEC 60529; IEC 60601-1-2; and EN 60601-1-2.

### I. Comparison Table

The following comparison table compares Brasseler GEM to the predicate device, Clio Prime, 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** | **Brasseler GEM** | **Clio Prime** |
|---|---|---|
| 510(k) Number | K221955 | K202664 |
| Manufacturer | RealCloud Imaging Inc. doing business as RealCloud Imaging | Sota Precision Optics, Inc. doing business as SOTA Imaging |
| Trade Name | Brasseler GEM10<br>Brasseler GEM15<br>Brasseler GEM20 | Clio Prime<br>Clio Pedo |
| Classification Name | Digital x-ray sensor | Digital x-ray sensor |
| Classification | Class II | Class II |
| Classification Panel/ Medical Specialty | Radiology/Dental | Radiology/Dental |
| Regulation Number | 21 C.F.R. §872.1800 | 21 C.F.R. §872.1800 |
| Product Code | MUH | MUH |
| Number of Sensors | 3 | 2 |
| Sensor Exterior Sizes | 36.36 mm x 24.53.mm<br>38.83 mm x 29.63 mm<br>41.80 mm x 30.48 mm | 36.31 mm x 30.42 mm<br>41.76 mm x 30.42 mm |
| Sensor Imaging Sizes | 30.26 mm x 20.32 mm<br>33.15 mm x 26.25 mm<br>36.08 mm x 26.25 mm<br>All with four clipped corners | 30.26 mm x 20.32 mm<br>36.08 mm x 26.25 mm<br>All with four clipped corners |
| Overall Imaging Areas | 615 mm2<br>870 mm2<br>947.1mm2 | 615.0 mm2<br>947.1 mm2 |
| Pixel Size | 19.5 µm | 19.5 µm |
| Imager Resolution | 1539 x 1026 pixels (1.70 M pixels)<br>1692 x 1324 pixels (2.2 M Pixels)<br>1842 x 1324 pixels (2.40 M pixels) | 1539 x 1042 pixels (1.70 M Pixels)<br>1842 x 1342 pixels (2.40 M Pixels) |
| X-Ray Resolution | 20+ visible lp/mm | 20+ visible lp/mm |
| Dynamic Range | 16,384:1 | 16,384:1 |
| Technology | CMOS | CMOS |

| | | |
|---|---|---|
| Scintillator Technology | Cesium Iodide | Cesium Iodide |
| Operating System | Microsoft Windows 7 and 10 | Microsoft Windows 7 and 10 |
| Extraoral source | x-ray system | x-ray system |
| Interface to PC | USB 2.0, Type A | USB 2.0, Type A |
| Cable Length | 1.9 m and 2.9 m | 1.9 m and 2.9 m |
| Power Consumption | 0.8 Watts Max | 0.8 Watts Max |
| Electrical Rating | DC 5V, 350 mA max | DC 5V, 350 mA max |
| Sterilization | Not suitable for sterilization | Not suitable for sterilization |
| Housing | IPx8 Equivalent ISO 10993-1 Biocompatible | IPx8 Equivalent ISO 10993-1 Biocompatible |
| Indications for Use | 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 patient. | Clio Prime is a USB-driven, digital intraoral x-ray sensor which is intended to acquire dental intraoral radiography images. Clio Prime shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intraoral radiographs. Clio Prime can be used either in combination with special positioning devices to facilitate positioning and alignment with an x-ray beam or Clio Prime can also be positioned by hand with the assistance of the patient. |

| | | |
|---|---|---|
| Intended Use | 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 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. | Clio Prime is intended for any dental practice that uses x-ray equipment for intraoral diagnostic purposes. Clio Prime 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 not part of this submission. When Clio Prime is to be used in a dental practice, an optional software will be necessary. Clio Prime is a USB-driven digital intraoral x-ray sensor which is intended to acquire dental radiographic images. Clio Prime must be operated by healthcare professionals who have been trained and are competent using various methods of acquiring radiographic images of dental anatomy. Clio Prime can be used with dental positioning devices and holders to assist with aligning an x-ray source beam with the sensor and anatomy. |

## J. Comparison of MTF of Brasseler GEM and MTF of Clio Prime

Brasseler GEM 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 Clio Prime which is the predicate device. The components used in Brasseler GEM are the exact same components used in predicate device Clio Prime. The sensor MTF versus spatial frequency for Brasseler GEM and the sensor MTF versus spatial frequency for the predicate device, Clio Prime, are identical.

## K. Comparison of DQE for Brasseler GEM and DQE of Clio Prime

On behalf of RealCloud Imaging, BAE Systems Imaging Solutions has compared the DQE for Brasseler GEM with the DQE of Clio Prime has determined that they are substantially equivalent to each other.

## L. Meaningful Differences

Brasseler GEM and Clio Prime are CMOS x-ray image sensors. RealCloud Imaging has compared the MTF and the DQE of Brasseler GEM to the MTF and the DQE of Clio Prime and has determined they are substantially equivalent to each other. Brasseler GEM is not only similar in performance as Clio Prime but is also safe and effective based on performance testing.

## M. Sterilization

Brasseler GEM is not sold as sterile. RealCloud Imaging recommends that usage of Brasseler GEM requires a hygienic barrier that meets ISO 10993 requirements for biocompatibility. There is foreseeable misuse where a clinician would place Brasseler GEM in the oral cavity without a barrier thereby exposing the housing of Brasseler GEM to the oral cavity.

## N. 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, Clio Prime. The biocompatibility of Brasseler GEM is based on the biocompatibility of the predicate device, Clio Prime. Both Brasseler GEM and the predicate device, Clio Prime, are intended to be used in the oral cavity by a trained clinician.

## O. SABIC Resin for Sensor Housing of Brasseler GEM

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

## P. Software Information

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

## Q. Risk Analysis

RealCloud Imaging used a specified a 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. RealCloud Imaging performed extensive risk analysis bench of Brasseler GEM 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.

## R. Comparison of Safety and Effectiveness of Brasseler GEM to Safety and Effectiveness of Clio Prime

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Using the above Comparison Table, Brasseler GEM can be compared to the predicate device, Clio Prime, 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 Brasseler GEM and Clio Prime with respect to indications and intended use.

## S. Performance Testing-Clinical

RealCloud Imaging performed a clinical performance testing to determine that Brasseler GEM performed as well or better than did the predicate device,

Clio Prime. RealCloud Imaging has provided clinical images. These clinical images provide further evidence in addition to the laboratory performance data that shows that the complete system works as intended.

## T. Conclusion

Sota Precision Optics, Inc. dba SOTA Imaging markets the predicate device, Clio Prime, under the cleared 510(k) Premarket Notification No. K202664. On behalf of RealCloud Imaging, BAE Systems Imaging Solutions has compared Brasseler GEM with the predicate device, Clio Prime, and has determined that they are substantially equivalent to each other in intended use, indications for use, safety and effectiveness, and technical characteristics.