Sota Precision Optics, Inc. dba SOTA Imaging
% Mr. Ed Johansen
Official Correspondent
W. Edward Johansen
1239 Stanford Street, #205
SANTA MONICA CA 90404

November 6, 2020

Re: K202664
Trade/Device Name: Clio Prime and Clio Pedo
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: September 12, 2020
Received: September 14, 2020

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202664

Device Name

Clio Prime and Clio Pedo

Indications for Use *(Describe)*

Clio Prime and Clio Pedo are USB-driven, digital intraoral x-ray sensors which are intended to acquire dental intraoral radiography images. Clio Prime or Clio Pedo shall be operated by healthcare professionals who are educated and competent to perform the acquisition of dental intraoral radiographs. Clio Prime or Clio Pedo can be used either in combination with special positioning devices to facilitate positioning and alignment with an x-ray beam, or Clio Prime or Clio Pedo can 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

510(k) Premarket Notification No. K202664

October 29, 2020

I. Corporation Information

Name: Sota Precision Optics, Inc. dba SOTA Imaging

Address: 1073 North Batavia Street, Suite B

Orange, California 92867

Telephone: (714) 532-6100

Official Correspondent: W. Edward Johansen

Telephone: (310) 795-7425

E-mail address: wedjohansen@msn.com

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

II. Identification of New Device

Owner/Operator: Sota Precision Optics, Inc. dba SOTA Imaging

Establishment Registration Number: 3000190675

Trade Name: Clio Prime and Clio Pedo

510(k) Premarket Notification Number: K202664

Common Name: Dental digital x-ray sensor

Classification Name: Extra-oral source x-ray system

Product Code: MUH

Class: II

Panel: Radiology

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

Manufacturer: SOTA Imaging

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

Sterilization Facility: Not Applicable

III. Identification of Predicate Device

Owner/Operator/Manufacturer: Dental Imaging Technologies Corporation

Establishment Registration Number: 2530069

510(k) Premarket Notification Number: K090458

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

Trade Name: DEXIS Platinum sensor and GENDEX GXS-700 sensors

Common Name: Dental intraoral x-ray sensor

Classification Name: Extra-oral source x-ray system

Product Code: MUH

Classification: Class II

Panel: Radiology

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

IV. Device Description

Clio Prime and Clio Pedo are USB-driven digital sensors designed for health care professionals already acquainted with the standard procedures for acquiring dental intra-oral radiographs. Digital x-ray imaging is an aide for diagnosis and should always be confirmed by the doctor using additional Clio Prime or Clio Pedo procedures and other diagnostic aides for confirmation. Clio Pedo is a smaller version of Clio Prime and is for pediatric use. The Clio Prime and Clio Pedo design uses advanced ergonomic principles with four beveled corners, a moderate profile, and a rounded casing providing enhanced comfort for patients. Clio Prime or Clio Pedo is positioned in the patient's mouth in the same manner as intra-oral film is positioned. Each of Clio Prime and Clio Pedo 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 Clio Prime or Clio Pedo through the standard USB port. Image analysis software is not part of the submission. For Clio Prime or Clio Pedo 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.

Clio Prime and Clio Pedo 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.

V. Indications for Use

Clio Prime and Clio Pedo are USB-driven, digital intraoral x-ray sensors which is intended to acquire dental intraoral radiography images. Clio Prime or Clio Pedo shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intraoral radiographs. Clio Prime or Clio Pedo can be used either in combination with special positioning devices to facilitate positioning and alignment with an x-ray beam, or Clio Prime or Clio Pedo can also be positioned by hand with the assistance of the patient.

VI. Intended Use

Clio Prime and Clio Pedo are intended for any dental practice that uses x-ray equipment for intraoral diagnostic purposes. It 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 or Clio Pedo is to be used in a dental practice, an optional software will be necessary.

VII. Performance Testing—Animal Study

SOTA Imaging did not perform an animal study performance testing.

VIII. Performance Testing—Clinical Study

SOTA Imaging a clinical study performance testing to determine that Clio Prime, and Clio Pedo performed as well or better than did the DEXIS Platinum sensor and GENDEX GXS-700 sensors. SOTA 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.

IX. Performance Testing—Bench Study

On behalf of SOTA Imaging Intertek performed an extensive bench testing on Clio Prime and Clio Pedo.

X. Comparison Table

The following comparison table compares Clio Prime and Clio Pedo to the predicates, the DEXIS Platinum sensor and the GENDEX GXS-700 sensors 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	DEXIS Platinum sensor and GENDEX GXS-700 sensors	Clio Prime and Clio Pedo
510(k) Number	K090458	K202664
Manufacturer	Dental Imaging Technologies Corporation	Sota Precision Optics, Inc. doing business as SOTA Imaging
Trade Name	DEXIS Platinum sensor and GENDEX GXS-700 sensors	Clio Prime and Clio Pedo
Classification Name	System, x-ray, extraoral source	System, x-ray, extraoral source
Classification Panel	Radiology	Radiology
Classification	Class II	Class II
Regulation Number	21 C.F.R. § 872.1800	21 C.F.R. § 872.1800
Indication for Use	The DEXIS Platinum sensor or the GENDEX GXS-700 sensors are USB-driven, digital intraoral x-ray sensors which are intended to acquire dental intraoral radiography images. The DEXIS Platinum sensor or the GENDEX GXS-700 sensors shall be operated by healthcare professionals who are educated and competent to perform the acquisition of dental intraoral radiographs. The DEXIS Platinum sensor or the GENDEX GXS-700 sensors can be used either in combination with	Clio Prime and Clio Pedo are USB-driven, digital intraoral x-ray sensors which are intended to acquire dental intraoral radiography images. Clio Prime or Clio Pedo shall be operated by healthcare professionals who are educated and competent to perform the acquisition of dental intraoral radiographs. Clio Prime or Clio Pedo can be used either in combination with special positioning devices to facilitate positioning and alignment with an x-ray beam, or Clio Prime or

	special positioning devices to facilitate positioning and alignment with an x-ray beam or the intraoral radiography images. The DEXIS Platinum sensor or the GENDEX GXS-700 sensors shall be operated by healthcare professionals who are educated and competent to perform the acquisition of dental intraoral radiographs. The DEXIS Platinum sensor or the GENDEX GXS-700 sensors can be used either in combination with special positioning devices to facilitate positioning and alignment with an x-ray beam, or the DEXIS Platinum sensor or the GENDEX GXS-700 sensors can also be positioned by hand with the assistance of the patient.	Clio Pedo can also be positioned by hand with the assistance of the patient.
Intended Use	The DEXIS Platinum sensor and the GENDEX GXS-700 sensors are indirect converting x-ray detectors, e.g. incident x-rays are	Clio Prime and Clio Pedo are USB-driven digital sensors which are intended to acquire dental intraoral radiography

	converted by a scintillating material into (visible) light, this light is coupled optically to a light detection imager based on CMOS technology. The design of the sensor assembly supports the automatic detection of the incident x-rays to generate digital images for dental intra-oral applications. The DEXIS Platinum sensor or the GENDEX GXS-700 sensors supports USB 2.0 and USB 1.1 connectivity to personal computers using a dedicated electronic assembly and a sensor software driver. The DEXIS Platinum sensor and the GENDEX GXS-700 sensors are USB-driven digital sensors which are intended to acquire dental intra-oral radiography images. The DEXIS Platinum sensor and GENDEX GXS-700 sensors shall be operated by healthcare professionals, who are educated and	images. Clio Prime or Clio Pedo shall be operated by healthcare professionals who are educated and competent to perform the acquisition of dental intraoral radiographs. Clio Prime or Clio Pedo 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. Clio Prime or Clio Pedo can be used with patients of any age, providing the correct positioning of the sensor in the patient mouth can be realized. Using Clio Prime or Clio Pedo is a suitable diagnostic method and may offer reduced radiation exposure compared to analog procedures. Furthermore, available software image enhancement tools may enhance sensitivity and

	competent to perform the acquisition of dental intra-oral radiographs. The DEXIS Platinum sensor and GENDEX GXS-700 sensors can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of the patient.	consequently reduce errors introduced by subjective analysis. Clio Prime or Clio Pedo can perform and achieve the same type of two-dimensional images as conventional (traditional) film sizes 0, 1 and 2. However cannot be used to, or as a substitution for extraoral or other types of dental x-ray. When using Clio Prime or Clio Pedo and software as a diagnostic aide, clinical experience and a combination of other diagnostic aides should be used to form a diagnosis and should not be solely relied upon for diagnosis.
Cable Length	2.8 meters 2.9 meters 2.9 meters	1.9 meters and 2.9 meters 1.9 meters and 2.9 meters
Product Code	MUH	MUH
Number of Sensors	3	2
Sensor Exterior Size	38.95 mm x 29.75 mm 37 mm x 25 mm 42 mm x 31 mm	36.31 mm x 24.49 mm 41.76 mm x 30.42 mm
Sensor Imaging Size	32.99 mm x 25.82 mm 30.01 mm x 20.00 mm 35.57 mm x 25.82 mm image area with four clipped corners	30.26 mm x 20.32 mm 36.08 mm x 26.25 mm image area with four clipped corners

Overall Imaging Area	820 mm2 600.2 mm2 918.4 mm2	615.0 mm2 947.1 mm2
Pixel Size	19.5 µm	19.5 µm
Imager Resolution	1692 by 1324 pixels (2.25M pixels) 1026 x 1539 pixels (1.58M pixels) 1324 x 1842 pixels (2.44M pixels)	1539 x 1042 pixels (1.60M Pixels) 1842 x 1342 pixels (2.47M 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
Interface to PC	USB 2.0, Type A Plug	USB 2.0, Type Plug
Operating System	Microsoft Windows XP© Microsoft and Windows Vista©	Microsoft Windows 7 and 10
Sterilization	Not suitable for sterilization	Not suitable for sterilization
Power Consumption	1.4 Watts Max	0.8 Watts Max
Electrical Rating	DC 5V, 350 mA max	DC 5V, 350 mA max
Housing	IP68 Biocompatible	IPx8 Equivalent ISO 10993 biocompatible
Extraoral source	x-ray system	x-ray system
MTF	40% at 6.6 lp/mm	39% at 6.6 lp/mm

XI. Comparison of Safety and Effectiveness of the Predicate Devices, DEXIS Platinum Sensor and GENDEX GXS-700 Sensors to Safety and Effectiveness of Clio Prime and Clio Pedo

Using the above Comparison Table, Clio Prime and Clio Pedo can be compared to the predicate devices, DEXIS Platinum sensor and GENDEX GXS-700 sensors, 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 basisfor the determination of substantial equivalence.

XII. Comparison of MTF for the DEXIS Platinum Sensor and the GENDEX GXS-700 Sensor with MTF of Clio Prime and Clio Pedo

Clio Prime and Clio Pedo use components from contract manufacturer BAE Systems Imaging Solutions, a division of BAE Systems Inc., which is also responsible for the manufacture of the DEXIS Platinum sensor and the GENDEX GXS-700 sensors which are the predicate devices. The components used in Clio Prime and Clio Pedo are a combination of identical components and incremental improvements over the components in the DEXIS Platinum sensor and the GENDEX GXS-700 sensors. SOTA Imaging believes that by comparing the MTF of the DEXIS Platinum sensor and the GENDEX GXS-700 sensors with the MTF of Clio Prime and Clio Pedo they are all substantially equivalent to each other.

XIII. Meaningful Differences

The DEXIS Platinum sensor, the GENDEX GXS-700 sensors, Clio Prime, and Clio Pedo are all CMOS x-ray image sensors. SOTA Imaging has compared the MTF of the DEXIS Platinum sensor and the GENDEX GXS-700 sensors with the MTF of Clio Prime and Clio Pedo and has determined they are substantially equivalent to each other. Clio Prime and Clio Pedo are not only similar in performance as the DEXIS Platinum sensor and the GENDEX GXS-700 sensors, but is also safe and effective based on performance testing in accordance with the following reference standards: ISO 14971; ANSI AMI ES 60601-1; IEC 62304; IEC 60529; IEC 60601-1-2; EN 60601-1-2; and ISO 10993-1.

XIV. Biocompatibility

BAE Systems Imaging Solutions uses a different SABIC resin than SABIC's ULTEM resin for the sensor housing of the DEXIS Platinum sensor and the housing of the GENDEX GXS-700 sensors. BAE Systems Imaging Solutions uses SABIC's ULTEM resin for the sensor housing of Clio Prime and the housing of Clio Pedo.

Clio Prime and Clio Pedo are intended to be used in the oral cavity by a trained clinician. During a typical full mouth series, Clio Prime or Clio Pedo is repeatedly placed in the oral cavity and removed or repositioned a total of 18 times. The average time of each insertion is less than 1 minute and the total time for a complete set of images is less than 10 minutes. This places Clio Prime and Clio Pedo in the category of “Limited Exposure” defined by Table A.1 of the CDRH Guidance Document dated June 16, 2016. With Mucosal contact the sensor shall meet the following requirements for biocompatibility—Cytotoxicity, Sensitization, and Irritation.

SOTA Imaging recommends that usage of Clio Prime or Clio Pedo requires a hygienic barrier that meets ISO 10993 requirements for biocompatibility. There is foreseeable misuse where a clinician would place the sensor in the oral cavity without a barrier, exposing the sensor housing to the oral cavity.

Biocompatible testing for the subject devices, Clio Prime and Clio Pedo, is not warranted because in the dental clinic there are not direct or indirect patient-contacting components in the subject devices. They are covered with a single-use protective barrier prior to each use just like the predicate devices, the DEXIS Platinum sensor and the two GENDEX GXS-700 sensors.

XV. Conclusion

On behalf of SOTA Imaging, BAE Systems Imaging Solutions has compared the MTF for the DEXIS Platinum sensor and the GENDEX GXS-700 sensors with the MTF of the Clio Prime and Clio Pedo and has determined that they are substantially equivalent to each other.

Clio Prime and Clio Pedo are substantially equivalent to the legally marketed DEXIS Platinum sensor and the legally marketed GENDEX GXS-700 sensors in the United States. Clio Prime and Clio Pedo are substantially equivalent in intended use, indications for use, safety and effectiveness, and technical characteristics to the DEXIS Platinum sensor and the GENDEX GXS-700 sensors which Dental Imaging Technologies Corporation markets under the cleared 510(k) Premarket Notification No. K090458. Clio Prime and Clio Pedo are not only similar in performance as the DEXIS Platinum sensor and the GENDEX GXS-700 sensors, but are also safe and effective based on performance testing in accordance with the following reference standards: ISO 14971; ANSI AMI ES 60601-1; IEC 62304; IEC 60529; IEC 60601-2; EN 60601-1-2; and ISO 10993-1.