November 21, 2023

Dental Imaging Technologies Corporation
℅ Ms. Anuradha Moholkar
Regulatory Affairs Specialist
450 Commerce Drive
QUAKERTOWN, PA 18951

Re: K233053
Trade/Device Name: DEXIS Ti2 Intraoral Sensor, DEXIS IXS Size 1 Intraoral Sensor, DEXIS IXS Size 2 Intraoral Sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: September 25, 2023
Received: September 25, 2023

Dear Ms. Moholkar:

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,

for Lu Jiang, 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)*
K233053

Device Name
DEXIS Ti2 Intraoral Sensor, DEXIS IXS Size 1 Intraoral Sensor, DEXIS IXS Size 2 Intraoral Sensor

Indications for Use *(Describe)*

The DEXIS sensor is a USB- driven digital sensor which is intended to acquire dental intra- oral radiographic images. The DEXIS sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The DEXIS sensor 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.

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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K233053 510(k) Summary

Prepared on: 2023-10-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dental Imaging Technologies Corporation
Applicant Address	450 Commerce Drive Quakertown PA 18951 United States
Applicant Contact Telephone	2678102911
Applicant Contact	Ms. Anuradha Moholkar
Applicant Contact Email	anuradha.moholkar@envistaco.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DEXIS Ti2 Intraoral Sensor; DEXIS IXS Size 1 Intraoral Sensor; DEXIS IXS Size 2 Intraoral Sensor
Common Name	Extraoral source x-ray system
Classification Name	System, X-Ray, Extraoral Source, Digital
Regulation Number	872.1800
Product Code	MUH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172918	DEXIS Titanium, KaVo IXS HD (Size 1, Size 2)	MUH

Device Description Summary

21 CFR 807.92(a)(4)

Device Description Summary:
The DEXIS Sensors are an indirect converting x-ray detector, e.g. incident x-rays are 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 Sensors support USB2.0 and USB 3.x connectivity to personal computers using a dedicated electronic assembly and a sensor software driver.
The software and firmware for the subject device are similar to the software and firmware for the predicate device and both have a Moderate level of concern. The software performs only basic functions of image capture and transfer to a computer. The software does not perform any medical image manipulation such as image enhancements as these are expected to be performed in the dental viewing software(s) used in conjunction with the subject device.
The subject device DEXIS sensor refers to the dental intra-oral detector. The x-ray generator (an essential component for a fully-functional dental x-ray system) is not part of the submission.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The DEXIS sensor is a USB-driven digital sensor which is intended to acquire dental intraoral radiographic images. The DEXIS sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radio-graphs. The DEXIS sensor 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Indications for Use is identical to the Indications for Use of the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

DEXIS Ti 2, DEXIS IXS (Size 1, Size 2) design or technical features have not been significantly modified since its clearance in 2017 (Predicate Device K172918).

This section provides the substantial equivalence rationale for DEXIS Ti 2, DEXIS IXS (Size 1, Size 2) and the respective predicate device with regards to Indications for Use, Technology, and Performance Testing. As described in this section, the differences between the subject device and the predicate do not raise different questions of substantial equivalence.

Details of the similarities between subject and predicate devices:
The similarities between Subject Device and the Predicate Device are the Indications for Use as well as the Subject Device uses CMOS as Fundamental Technology which is same as the Predicate Device. The Subject Device has same Sensor Exterior Dimensions and Sensor Active Imaging Area as the Predicate Device. Also, the pixel size of 19.5um, dynamic range, and Scintillator Technology for Subject Device is same as the Predicate Device.

At all points of MTF measurement (2, 5, 10, 15, 20 lp/mm), both the subject and predicate devices meet specification. Also, both the subject and predicate devices have an X-ray Resolution of 20+ visible lp/mm which meets the device specification. Furthermore, the MTF analysis indicates that maximum resolution of 22 lp/mm is achieved by both predicate and subject devices which is above the device specification.

Details of the differences between subject and predicate devices:
There are no major differences however there are two minor differences between Subject Device and Predicate Device. The Sensor cable length of the Subject Device is reduced from 3m to 2.5m and the Subject Device supports USB 3.x connectivity in addition to USB 2.0 connectivity to personal computers.

Conclusion:
Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, DEXIS Ti 2, DEXIS IXS (Size 1, Size 2) are deemed to be substantially equivalent to the predicate devices as it satisfies all criteria of substantial equivalence and does not raise new concerns regarding substantial equivalence: (1) Indications for Use, (2) Technological Characteristics, and (3) Performance Data. DEXIS Ti 2, DEXIS IXS (Size 1, Size 2) do not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is substantial equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance Testing Bench:
Non-Clinical performance bench testing according to international standards and FDA recognized consensus standards for Extraoral source x-ray system has been conducted to determine conformance in regards to:
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text); Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02; Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION; Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 60601-2-65 Edition 1.1 2017-05 CONSOLIDATED VERSION; Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment

- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION; Medical device software - Software life cycle processes
- ISO 10993-5 Third edition 2009-06-01; Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01; Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 14971 Third Edition 2019-12; Medical devices - Application of risk management to medical devices
- IEC 61223-3-4 First edition 2000-03; Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray
- EC /TR 60601-4-2 Edition 1.0 2016-05; Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Also, the subject device has an X-ray Resolution of 20+ visible lp/mm which meets the device specification. Furthermore, the MTF analysis indicates that maximum resolution of 22 lp/mm is achieved by the subject device which is above the device specification.

Performance Testing Clinical:
Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

Conclusion:
Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the DEXIS Ti 2, DEXIS IXS (Size 1, Size 2) Sensors are deemed to be substantially equivalent to the predicate device.