Dentium Co., Ltd (ICT Branch)
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7707 Fannin St. Ste 200, V111
HOUSTON TX 77054

June 10, 2020

Re: K201247
Trade/Device Name: Intra Oral Sensor (model: IOX 1/ IOX 2)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, MUH
Dated: May 4, 2020
Received: May 11, 2020

Dear Dave Kim:

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)*
K201247

Device Name
Intra Oral Sensor (model: IOX 1 / IOX 2)

Indications for Use *(Describe)*

Intra Oral Sensor (model: IOX 1 / IOX 2) is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, views 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K201247

The summary of 510(k) is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date:	6/8/2020
APPLICANT	Dentium Co.,Ltd (ICT Branch)
ADDRESS	76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16229 Republic of Korea ++82-70-7098-6932
Contact Person	Mr. Sang Woo Lee (swlee1@dentium.com)
Official Correspondent	Dave Kim, MBA Mtech Group 7707 Fannin St. Ste 200, Houston, TX 77054 TEL : 713-467-2607 Email : davekim@mtech-inc.net

Device Name

Trade Name:	Intra Oral Sensor
Model Name:	IOX1 / IOX2
Regulation Name:	Stationary X-ray System
Regulatory Number:	21 CFR 892.1680
Regulatory Class:	II
Product code:	MQB, MUH
Panel:	Radiology

Predicate device

Predicate device (K143000)

Trade/Device Name:	RIO Sensor (RIS 500)
Regulation Number:	21 CFR 892.1680
Regulation Name:	Stationary x-ray system
Regulatory Class:	II
Product Code:	MQB

Reference Device (K090526)

Trade/Device Name:	EzSensor
Regulation Number:	21 CFR 872.1800
Regulation Name:	Extraoral source X-ray system
Regulatory Class:	II
Product Code:	MUH

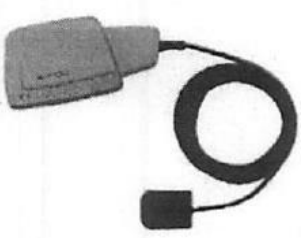
Description

Intraoral Sensor (model: IOX 1 / IOX 2) by Dentium is a medical device that acquires digital images by detecting subject information through X-rays and converting them into electrical image signals to identify teeth and tissues in the mouth. The product consists of the Intraoral Sensor, USB Memory, Sensor Holder, Silicon Cover and Quick Guide.

Indication for use

Intra Oral Sensor (model: IOX 1 / IOX 2) is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, views and manipulated for diagnostic use by dentists.

Statement of Substantial Equivalence

Parameter	Proposed Device	Predicated Device	Reference Device
Manufacturer	DENTIUM Co., Ltd	RAY Co., Ltd	E-WOO Technology Co., Ltd.
Device Name	Intra Oral Sensor IOX1 / IOX2	RIS500	EzSensor
510(K) Number	K201247	K143000	K090526
Feature			
Indications for use	Intra Oral Sensor (model: IOX 1 / IOX 2) is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, views and manipulated for diagnostic use by dentists.	This system is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, views and manipulated for diagnostic use by dentists.	Indicated for intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentist.

Device Description	Intra Oral Sensor (model: IOX 1 / IOX 2) is a medical device that acquires digital images by detecting subject information through X-rays and converting them into electrical image signals to identify teeth and tissues in the mouth. The product consists of the Intraoral Sensor, USB Memory, Sensor Holder, Silicon Cover and Quick Guide	RIOSensor(Model RIS500) is intended to acquire real-time, clinical digital intraoral X-ray images using a solid-state imaging sensor. This system consists of the CMOS sensor and software for image display. This system senses the onset of the X-ray exposure and automatically acquires and save the image data to a PC (software).	The EzSensor is a solid state x-ray imager designed for dental radiographic applications, The EzSensor provides digital image capture for conventional film/screen radiographic dental examinations. The device is used to replace radiographic film/screen system in general dental diagnostic procedures. The captured digital image is transferred to Personal Computer via USB interface port
Sensor Dimension	IOX 1: 36.7 x 24 mm IOX 2: 42.6 x 29.1 mm	Size 1: 39x25 mm Size 2: 42x30 mm	Size "1.0": 35.7x25.2 mm Size "1.5": 38.7x29.2 mm
Sensor Thickness	5.1 mm	5.6 mm	4.95mm
Active Area(mm)	IOX 1: 20 x 30 mm IOX 2: 26 x 36 mm	Size 1: 39x25 Size 2: 42x30	Size "1.0": 20.02x30.03 Size "1.5": 24.08x31.85
USB Module	Integrated USB 2.0 module	Integrated USB 2.0 module	Integrated USB 2.0 module
Pixel size	20x20 μm	20x20 μm	35x35 μm
Pixel Matrix	IOX 1: 1000x1500 pixel IOX 2: 1280x1801 pixel	Size 1: 1000x1500 pixel Size 2: 1300x1700 pixel	Size "1.0": 572x858 pixel Size "1.5": 686x944 pixel
Pixel Pitch	20x20 μm	20x20 μm	35x35 μm
Theoretical Resolution	25 lp/mm	25 lp/mm	14.3 lp/mm
MTF	More than 30 % at 6 lp/mm	More than 30% at 6 lp/mm	More than 30% at 6 lp/mm
DQE	More than 40 % at 2.5 lp/mm	More than 40% at 2.5 lp/mm	More than 40% at 2.5 lp/mm

The intended use, constructions, construction materials, technical characteristics and safety characteristics between Intra Oral Sensor (model: IOX 1 / IOX 2) and its predicate device are same.

The differences include the digital X-ray imager sizes and image viewing software. Performance testing was conducted for the subject device to access whether or not the parameter required for functionalities related to imaging properties of the dental X-ray device meets the designated acceptance criteria. All test results were satisfactory.

Safety and Effectiveness Information:

Electrical, mechanical and environmental safety testing according to standard of IEC 60601-1(2005+ CORR.1(2006)+CORR.2(2007), AMD 1: 2012 was performed.
EMC testing was conducted in accordance with the standard IEC 60601-1-2(2014).

The software of Intra Oral Sensor (model: IOX 1 / IOX 2) has been validated according to FDA "*Guidance for the Content d Premarket Submissions for Software Contained in Medical Devices"* and applicable requirements contained in the guidance document.

Bench testing was conducted according to FDA Guidance *"Format for Traditional and Abbreviated 510(k)s, section 18, Performance Testing – Bench"*
Bench testing is used to assess whether or not the parameter measured required for describing functionalities related to imaging properties of the dental X-ray device and patient dosage satisfies the designated tolerance.

Performance (Imaging performance) testing was conducted according to standard of IEC 61223-3-4.
All test results were satisfactory.

Non-clinical considerations were conducted in accordance with FDA Guidance *"Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices"*.
All test results were satisfactory.
The tests include the MTF(Modulation Transfer Function) and DQE(Detective Quantum Efficiency) of detector. MTF of detector shows the resolution more than 30 % at 6 lp/mm and The DQE of detector shows the resolution more than 40 % at 2.5 lp/mm.
Base on the Non-Clinical Test report, Even though the pixel size and active area of predicate detectors are different, the diagnostic image quality of Intra Oral Sensor (model: IOX 1 / IOX 2) is substantially equivalent to that of predicate device and there is no significant difference in efficiency and safety.

Clinical Data: Not required for a finding of substantial equivalence.

Conclusions

In accordance with the federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Dentium Co., Ltd concludes that the Intra Oral Sensor (model: IOX 1 / IOX 2) present no new risk and perform its intended use substantially equivalent to the predicate device.