KaVo Dental Technologies, LLC
% Mr. Frank Ray
Regulatory Affairs Manager
11727 Fruehauf Drive
CHARLOTTE NC 28273

December 18, 2017

Re: K172918
Trade/Device Name: DEXIS Titanium, KaVo IXS HD (Size 1, Size 2)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: September 15, 2017
Received: November 16, 2017

Dear Mr. Ray:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K172918

Device Name
DEXIS Titanium, KaVo IXS HD (Size 1, Size 2)

Indications for Use *(Describe)*

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

Section V – 510(k) Summary
for
Digital Intraoral Sensor
DEXIS Titanium, Kavo IXS HD (Size 1, Size 2)

1. Submitter Information:

KaVo Dental Technologies, LLC
11727 Fruehauf Drive
Charlotte, NC 28273

Contact Person: Frank Ray
Telephone Number: (704) 587-7227
Fax Number: (704) 587-7250

Date Prepared: November 15, 2017

2. Device Name:

- Proprietary Name: DEXIS Titanium, Kavo IXS HD (Size 1, Size 2)
- Common Name: System, x-ray, extraoral source, digital
- Classification Name: Extraoral source x-ray system
- CFR Number: 872.1800
- Device Class: II
- Product Code: MUH

3. Predicate Device:

- Proprietary Name: DEXIS Sensor - (K090458)
- Common Name: System, x-ray, extraoral source, digital
- Classification Name: Extraoral source x-ray system
- CFR Number: 872.1800
- Device Class: II
- Product Code: MUH

4. Device Description:

The DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral 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 Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors supports USB2.0 connectivity to personal computers using a dedicated electronic assembly and a sensor software driver.

Per the Guidance for Industry and FDA Staff; Bundling Multiple Devices or Multiple Indications in a Single Submission, dated June 22, 2007, KaVo Dental Technologies, LLC is bundling the 3 sensor models listed below in Table 5.1. These 3 models of digital intraoral sensor only differ in branding, size and external industrial design (e.g. chamfered corners, angled USB cable exit), the main components are identical, though the layering is slightly adjusted due to the size of the housing and are cosmetic in nature. The device description and intended use are identical for all 3 proposed models listed below.

Table 5.1

Brand	Model Name	Size Differentiation	Housing Design Differentiation
DEXIS	DEXIS Titanium	Size 1.5	Chamfered corners, angled USB cable exit
KaVo	KaVo IXS HD – Size 1	Size 1	Rounded Corners, parallel USB cable exit
KaVo	KaVo IXS HD – Size 2	Size 2	Rounded Corners, parallel USB cable exit

Accessories:

The DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors have optional accessories/devices as listed in table 5.2 below. The barrier/sheaths have already been cleared by the FDA and contain their own labeling indicating they are disposable devices and the six Holders are Class I Exempt devices. Performance Bench Testing has been performed on all Device / Accessories. Also, KaVo Dental Technologies, LLC has quality system processes implemented for risk assessment for devices manufactured in compliance with ISO 14971:2007. This includes the DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors with the Devices / Accessories listed below in Table 5.2. The Risk Management File was reviewed by our test house Intertek as part of obtaining 60601-1 certification. All Devices/Accessories in table 5.2 are non-electrical.

TABLE 5.2

Device / Accessory	Device Description	Manufacturer	Product Code	510(k) Clearance
Sheath, Positioning System Barrier	Dental barriers and sleeves	Pac-Dent International	PEM	K151123
Sheath, Universal Sensor Barrier	Dental barriers and sleeves	Pac-Dent International	PEM	K151123
Anterior Holder	Dental X-ray film holder	KaVo Dental Technologies, LLC	EGZ	510(k) Exempt
Posterior Holder	Dental X-ray film holder	KaVo Dental Technologies, LLC	EGZ	510(k) Exempt
Horizontal Bitewing Holder	Dental X-ray film holder	KaVo Dental Technologies, LLC	EGZ	510(k) Exempt
Vertical Bitewing Holder	Dental X-ray film holder	KaVo Dental Technologies, LLC	EGZ	510(k) Exempt
Hand-Held Holder	Dental X-ray film holder	KaVo Dental Technologies, LLC	EGZ	510(k) Exempt
Endo Holder	Dental X-ray film holder	KaVo Dental Technologies, LLC	EGZ	510(k) Exempt
DEXIS Imaging Suite	System, Imaging Acquisition Software	DEXIS, LLC	LLZ	K090431

Principle of Operation:

The DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors are a digital intraoral sensor that utilizes scintillating material to convert incident x-rays into visible light coupled optically to a light detection imager based on CMOS technology. X-ray images are acquired when x-ray photons generated by an external x-ray source penetrate a patient's facial structure and impinge on the sensor which is then transferred via USB to a computer running an imaging software program. The digital x-ray sensor serves the same basic function as traditional x-ray film. The firmware controls the on-board function of the FPGA, and the software drivers provides image reconstruction, data transmission through USB, and interface with a dental imaging software for basic sensor management functionality.

The basic sensor management SW functionality contains the following:

- USB plug-n-play event handling for connected sensor(s) to PC
- Monitor sensor status
- Activate sensor for x-ray detection
- Monitor sensor for x-ray detection
- Transfer image from sensor to PC
- Basic Image Correction

The DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral require Dental Imaging Acquisition Software such as DEXIS Imaging Suite (K090431) to be operational. The Dental Imaging Acquisition Software is the Graphic User Interface (GUI) used by healthcare professionals to collect images and perform clinical diagnosis.

5. Indications for Use:

The DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensor is a USB-driven digital sensor which is intended to acquire dental intraoral radiographic images. The DEXIS / KaVo sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The DEXIS / KaVo 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.

6. Description of Substantial Equivalence:
Technological Characteristics:

The device comparison table below (Table 5.3) compares the DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors to one (1) other legally marketed Class II device DEXIS Sensor (K090458) which was granted marketing clearance by the FDA.

The DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors has the same intended use and technological characteristics as compared to the predicate device DEXIS Sensor (K090458). The changes raise no new questions of substantial equivalence.

There are 3 models of digital intraoral sensor described in this 510(k) submission and the only differences between the models are the sizes and external industrial design (e.g. chamfered corners, angled USB cable exit), the main components are identical, though the layout is slightly adjusted due to the size of the housing.

The proposed DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors has been determined to be substantially equivalent to the predicate device, the DEXIS Sensor (K090458) and shares the same intended use and fundamental technology as the predicate. The

differences do not render the device NSE because the performance tests demonstrate that the differences in technological characteristics do not raise different questions regarding substantial equivalence to the predicate device. Hence, the DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors are substantial equivalent to the DEXIS Sensor (K090458).

Table 5.3

Descriptive Information	**Proposed Device**			**Predicate Device DEXIS Sensor - K090458**
	DEXIS Titanium	**KaVo IXS HD Size 1**	**KaVo IXS HD Size 2**	
Regulation No.	21 CFR 872.1800			21 CFR 872.1800
Classification Name	Extraoral source x-ray system			Extraoral source x-ray system
Regulation Class	II			II
Product Code	MUH			MUH
Trade Name	DEXIS	KaVo		DEXIS Sensor
Common Name	Digital Intraoral X-ray Sensor			Digital Intraoral X-ray Sensor
Indications for Use	The DEXIS / KaVo sensor is a USB-driven digital sensor which is intended to acquire dental intra-oral radiographic images. The DEXIS / KaVo sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The DEXIS / KaVo 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.			The DEXIS Sensor is a USB-driven digital sensor which is intended to acquire dental intra-oral radiography 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.

Device Description	The DEXIS Titanium / KaVo IXS HD Intraoral 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 Titanium / KaVo IXS HD Intraoral Sensors supports USB2.0 connectivity to personal computers using a dedicated electronic assembly and a sensor software driver.			The DEXIS sensor is 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 sensor supports USB2.0 and USB 1.1 connectivity to personal computers using a dedicated electronic assembly and a sensor software driver.
Fundemental Technology	CMOS			CMOS
Sensor Exterior Dimension (mm)	39.9mm x 29.8mm	37.0mm x 25.2mm	42.3mm x 30.4mm	38.9mm x 29.7mm
Sensor Active Imaging Area	33.0mm x 26.0mm with four clipped corners	30.1mm x 20.2mm with four clipped corners	36.0mm x 26.0mm with four clipped corners	33.0 mm x 25.8 mm with four clipped corners
Pixel Size	19.5um			19.5um
Dynamic Range	4,096:1			16,384:1
Image Resolution	1692 x 1324 pixels	1539 x 1026 pixels	1842 x 1324 pixels	1692 x 1324 pixels
USB Cable exit	35° angled cable exit	0° parallel cable exit	0° parallel cable exit	35° angled cable exit
Corner design	Chamfered corners	Rounded corners	Rounded corners	Chamfered corners
Sensor Cable Length	3 m			2.8 m
X-ray Resolution	20+ visible lp/mm			20+ visible lp/mm
Scintillator Technology	Cesium Iodide (CsI) Scintillator			Cesium Iodide (CsI) Scintillator
SW Features	• USB 2.0 Communication • Noise Filtering • Binning • Basic Image Correction (Gain/Offset/Pixel Calibration) • Monitoring Sensor Health/State • Image Transmission			• USB 2.0 Communication • Noise Filtering • Binning • Basic Image Correction (Gain/Offset/Pixel Calibration) • Monitoring Sensor Health/State • Image Transmission
Interface to PC	USB Type A Plug			USB Type A Plug

Input electrical power	5.0V / 0.5W via USB	5.0V / 350mA max via USB
Exposure method	X-Ray Monitor Mode	X-Ray Monitor Mode
Communication standard	USB 2.0	USB 1.1 and 2.0
Motion sensing capability	Yes	N/A
Consensus Standards	IEC 60601-1 IEC 62366-1 IEC 60601-2-65 IEC 60601-1-2 IEC 62304	IEC 60601-1 IEC 60601-2-65 IEC 60601-1-2

Non-Clinical Test Data:

Performance bench testing according to international standards for Extra-oral source x-ray system (Sensors) has been conducted to determine conformance in regards to:

- Biocompatibility has been completed for the applicable components.
- Software documentation for moderate level of concern per the FDA Guidance Document for Software Contained in Medical Devices.
- Electrical Safety testing, including Electromagnetic Compatibility, have been performed by Intertek Testing Services.
- Comparative performance testing of the functions of the accessories as compared to the cleared stand-a-lone device.

Furthermore, the performance of the DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors has been verified utilizing the following standards in Table 5.4 below:

TABLE 5.4

Item	Standard	Year & Edition	Description
1.	IEC 60601-1	2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
2.	AAMI / ANSI ES60601-1	2005/(R)2012 and C1:2009/ (R)2012 and, A2:2010/(r)2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
3.	CSA C22.2 # 60601-1	2014 (3rd) 2014-01-01	Medical Electrical Equipment - Part 1: General Req. for Basic Safety & Essential Perf.; Cor. 2: 2011
4.	IEC 60601-1-2	2014 (4th Ed.) 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
5.	IEC 60601-1-6	2010	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability.
6.	IEC 60601-2-65	2012 (1st Ed.) 2012-09	Medical electrical equipment Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment.
7.	ISO 10993-1	2009 (4th) 2009-10-15	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [including: technical corrigendum 1 (2010)].
8.	ISO 10993-5	2009 – AAMI ANSI ISO	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
9.	ISO 10993-10	2010 (3rd ed) 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
10	AMMI / ANSI IEC 62304	2006	Medical device software - Software life cycle processes.
11	AMMI ANSI IEC 62366	2007/(R)2013 +A1	Medical devices - Application of usability engineering to medical devices.
12	ISO 14971	2007	Medical devices - Application of risk management to medical devices.

Hence the DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors demonstrates substantial equivalence.

Clinical Performance Data:

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 as to Substantial Equivalence:

Based on a comparison of intended use, indications, technological characteristics, principle of operation, features and performance data, the DEXIS Titanium, Kavo IXS HD (Size 1, Size 2) intraoral sensors are deemed to be substantially equivalent to the predicate device.