Durr Dental SE
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

March 19, 2021

Re: K203116
Trade/Device Name: SensorX
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: February 4, 2021
Received: February 9, 2021

Dear Mr. Kamm:

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)*
K203116

Device Name
SensorX

Indications for Use *(Describe)*
The intraoral sensor is intended to convert x-ray photons into electronic impulses that may be stored, viewed 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.

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510(k) Summary, DÜRR DENTAL SE K203116

This Traditional 510(k) is being submitted in accordance with the requirements of 21 CFR §807.92 and the FDA Guidance *"Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices"* issued on September 1, 2016.

1. Date Summary Prepared: February 4, 2021

2. Submitter's Identification:

Submitter's Identification:	**DÜRR DENTAL SE** Höpfigheimer Str. 17 74321 Bietigheim-Bissingen Germany Phone: + 49 (0) 7142 70 5-0 Fax: + 49 (0) 7142 705-500 E-Mail: info@duerr.de www.duerrdental.com	Establishment Registration Name in FURLS: **Duerr Dental SE**
Establishment Registration Number:	3015509619	
Submitter's Contact:	Mr. Oliver Lange Director of Quality Management DÜRR DENTAL SE Höpfigheimer Str. 17 74321 Bietigheim-Bissingen, Germany Phone: + 49 (0) 7142 70 5-190 Email: oliver.lange@duerrdental.com	
U.S. Agent & Contact:	Mr. Joseph Latkowski Director of Quality and Regulatory Air Techniques, Inc. 1295 Walt Whitman Road Melville, NY 11747, USA U.S. Phone: 516-214-5574 E-Mail: Joseph.Latkowski@airtechniques.com	

3. Identification of Subject Device:

Trade /Proprietary Name:	SensorX
Device:	System, x-ray, extraoral source, digital
Regulation Description:	Extraoral source x-ray system
Regulation Medical Specialty:	Dental
Review Panel:	Radiology
Product Code:	MUH
Regulation Number:	872.1800
Device Class:	II

4. Predicate Device

510(k) Number:	K172918
Manufacturer:	KaVo Dental Technologies, LLC
Trade /Proprietary Name:	DEXIS Titanium, KaVo IXS HD (Size 1, Size 2)
Device:	System, x-ray, extraoral source, digital
Regulation Description:	Extraoral source x-ray system
Regulation Medical Specialty:	Dental
Review Panel:	Radiology
Product Code:	MUH
Regulation Number:	872.1800
Device Class:	II

5. Device Description

The subject device SensorX device is an intraoral x-ray sensor for dental applications. It detects the x-rays and performs the image acquisition, digitizes the image and makes it available for the PC. The x-ray sensor is connected to the computer via the sensor cable, and if required, the USB extension.

The x-ray sensor is equipped with protective cover sheaths (previously 510(k) cleared) and placed in the mouth of the patient. For patient comfort, the ergonomic design is based on human intraoral anatomy:

Figure 1 – SensorX application

SensorX enables high resolution with a minimum radiation dose. It is connected to a computer to produce an image almost instantaneously following exposure. The primary advantage of direct sensor systems such as SensorX, is the speed with which images are acquired. SensorX is activated via the imaging software VisionX (K192743) OR DBSWIN (K203287).

6. Indications for use.

The intraoral sensor is intended to convert x-ray photons into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.

7. Description of Substantial Equivalence: Technological Characteristics:

The device comparison table below compares the Predicate Device: K172918 KaVo Dental Technologies, LLC to our proposed SensorX devices. Our device has the same intended use and technological characteristics as compared to the predicate device. The small differences do not raise any questions of substantial equivalence. The physical sizes are similar. The technologies are identical. The pixel sizes are nearly identical. The required computer and computer interfaces are identical. Therefore the DÜRR DENTAL SE SensorX is substantially to the equivalent KaVo device.

8. Summary of the technological characteristics compared to the predicate devices

Characteristics:	**Predicate Device: K172918 KaVo Dental Technologies, LLC**			**Subject Device: DÜRR DENTAL SE**	
Device Name	**DEXIS Titanium**	**KaVo IXS HD Size 1**	**KaVo IXS HD Size 2**	**SensorX Size 1**	**SensorX Size 2**
Indications for Use	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 be also positioned by hand with assistance of the patient.			The intraoral sensor is intended to convert x-ray photons into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists. (Same indication as predicate but simplified wording)	

Characteristics:	Predicate Device: K172918 KaVo Dental Technologies, LLC	Subject Device: DÜRR DENTAL SE
Device Picture		
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 support USB2.0 connectivity to personal computers using a dedicated electronic assembly and a sensor software driver.	The subject device SensorX device is an intraoral x-ray sensor for dental applications. It detects the x-rays and performs the image acquisition, digitizes the image and makes it available for the PC. The x-ray sensor is connected to the computer via the sensor cable, and if required, the USB extension. The x-ray sensor is equipped with protective cover sheaths (previously 510(k) cleared) and placed in the mouth of the patient. For patient comfort, the ergonomic design is based on human intraoral anatomy.

Characteristics:	Predicate Device: K172918 KaVo Dental Technologies, LLC			Subject Device: DÜRR DENTAL SE	
				SensorX enables high resolution with a minimum radiation dose. It is connected to a computer to produce an image almost instantaneously following exposure. The primary advantage of direct sensor systems such as SensorX, is the speed with which images are acquired. SensorX is activated via the imaging software VisionX (K192743) or DBSWIN (K203287).	
Fundamental Technology	CMOS			CMOS	
Sensor Exterior Dimension (mm)	39.9 x 29.8	37.0 x 25.2	42.3 x 30.4	39.0 x 27.4	44.7 x 33.1
Sensor Active Imaging Area (mm)	33.0 x 26.0 with four clipped corners	30.1 x 20.2 with four clipped corners	36.0 x 26.0 with four clipped corners	30.0 x 20.0 with four clipped corners	36.0 x 26.0 with four clipped corners
Pixel Size (µm)	19.5			19	
Dynamic Range	4,096:1			4,096:1	
Image Resolution	1692 x 1324 pixels	1539 x 1026 pixels	1842 x 1324 pixels	1580 x 1050 pixels	1896 x 1368 pixels
USB Cable Exit	35° angled cable exit	0° parallel cable exit	0° parallel cable exit	0° parallel cable exit	
Corner Design	Chamfered corners	Rounded corners	Rounded corners	Chamfered corners	
Sensor Cable Length	3 m			2.5 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			• USB 2.0 Communication • Noise Filtering	

Characteristics:	Predicate Device: K172918 KaVo Dental Technologies, LLC	Subject Device: DÜRR DENTAL SE
	• Binning • Basic Image Correction (Gain/offset/pixel Calibration) • Monitoring Sensor Health/State • Image Transmission	• 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	5.0 V / 0.5 W via USB	5.0 V / 0.5 W via USB
Exposure Method	X-Ray Monitor Mode	X-Ray Monitor Mode
Communication Standard (USB Model)	USB 2.0	USB 2.0
Motion Sensing Compatibility	Yes	Yes
Consensus Standards	IEC 60601-1 Basic Safety IEC 62366-1 Usability IEC 60601-2-65 Dental intra-oral X-ray equipment IEC 60601-1-2 Electromagnetic Compatibility IEC 62304 (Software testing eequirements)	IEC 60601-1 Basic Safety IEC 60601-1-6 Usability IEC 60601-2-65 Dental intra-oral X-ray equipment IEC 60601-1-2 Electromagnetic Compatibility IEC 62304 (Software testing requirements: Companion software sold separately, see chart below)

Imaging Software:

Imaging Software to be used with the Subject Device (SensorX):	510(k) Number:	Manufacturer:	Distributor
VisionX	K192743	**DÜRR DENTAL SE** In the 510(k) database referred to as “Durr Dental SE”	Air Techniques Inc.
DBSWIN	K203287	**DÜRR DENTAL SE** In the 510(k) database referred to as “Durr Dental SE”	Air Techniques Inc.

Protective covers sheaths must be used before placing the SensorX into the patient’s mouth. After usage the device must be cleaned and disinfected using the disinfectants and cleaning agents as listed in the installation and operating instructions.

Accessories to be used with the Subject Device (SensorX):

Barrier Sleeves / Barrier Envelopes:		510(k) Number:	Manufacturer:
TIDIShield® Digital x-ray sensor sheaths		K132953	TIDI PRODUCTS, LLC
100S	Digital sensor cover, 1 3/8" X 8", 500/box	K151123	Pac-Dent International, Inc.
100L	Digital sensor sleeve, 1 5/8" X 8", 500/box	K151123	Pac-Dent International, Inc.
DX-405	Fits Gendex Size 1, XDR size 1, 500pcs/box	K151123	Pac-Dent International, Inc.
DX-406	Fits Gendex Size 2, XDR Size 2, 500pcs/box	K151123	Pac-Dent International, Inc.
DX-999	Fits Dexis, Compares to TIDI # 20999, 500pcs/box	K151123	Pac-Dent International, Inc.
DX-978	Fits Kodak 6100 Size 1, Compares to TIDI # 20978, 500pcs/box	K151123	Pac-Dent International, Inc.
DX-979	Fits Kodak 6100 Size 2, Compares to TIDI # 20979, 500pcs/box	K151123	Pac-Dent International, Inc.
DX-890	Fits Sirona Size 2, Compares to TIDI # 20890, 500pcs/box	K151123	Pac-Dent International, Inc.
DX-904	Fits Sirona Size 1, Compares to TIDI # 20904, 500pcs/box	K151123	Pac-Dent International, Inc.
DX-824	Fits Schick Size 1, Compares to TIDI # 20824, 500pcs/box	K151123	Pac-Dent International, Inc.
DX-825	Fits Schick Size 2, Compares to TIDI # 20825, 500pcs/box	K151123	Pac-Dent International, Inc.
DX-819	Fits Suni/Lightyear Size 2, Compares to TIDI # 20819, 500pcs/box	K151123	Pac-Dent International, Inc.
PPE-248-2	#2 Barrier envelopes, 100pcs/box	K151123	Pac-Dent International, Inc.

9. Non-Clinical Data and Performance Testing

A clinical evaluation was performed. Furthermore, testing to the following IEC and DIN Standards was completed successfully:

Standard:	Standard Title:	Compliance Report Provided:
IEC 14971	Medical devices – Application of risk management to medical devices	• Risk Analysis
IEC 60601-1	Medical Electrical Equipment, Part l: General requirements for basic safety and essential performance	• IEC 60601-1 Safety Test Report
IEC 60601-1-2	Medical Electrical Equipment, Part l-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic Compatibility	• IEC 60601-1-2 EMC Test Report
IEC 60601-1-6	General requirements for basic safety and essential performance – Collateral standard: Usability	• IEC 60601-1-6 Test Report
IEC 60601-2-65	Medical electrical equipment - Part 2-65: Particular requirements for the basic	• User Manual

Standard:	Standard Title:	Compliance Report Provided:
	safety and essential performance of dental intra-oral X-ray equipment *Applicable sections for Sensor devices:* • 201.7.9.1 • 203.6.7.4	• Computer System Requirements
Software:		
System Integration Testing	Subject device integration was evaluated in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Risk management activities were documented.	• Cybersecurity for digital devices • Software System Test Report (Imaging Software: VisionX 2.4.10) • Software separately reviewed and cleared by FDA.
Reprocessing:		
Cleaning the device	Although the sensor does not normally come into contact with the patient, incidental contact is possible.	• Validation Report – Manual Reprocessing • User Manual Instructions
Biocompatibility:		
EN ISO 10993-5	Biological Evaluation Report	• Biological Risk Assessment • The device does not come into direct contact with the patient. A separate FDA cleared disposable plastic barrier is used.

In addition to the tests and reports cited above, actual dental images were provided which showed excellent resolution and contrast.

10. Clinical Data

Clinical data is not required for a finding of substantial equivalence.

11. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the similarity to the predicate device in terms of technology, performance and indications for use, DÜRR DENTAL SE concludes that the *SensorX* is substantially equivalent to the predicate device as described herein. The differences between the new device and the predicate device shown in the comparison table above do not raise any new questions about safety and effectiveness and so we consider it substantially equivalent to the predicate device.