Dürr Dental SE
℅ Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

October 7, 2020

Re: K202633
Trade/Device Name: ScanX Edge
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: September 1, 2020
Received: September 11, 2020

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)*
K202633

Device Name
ScanX Edge

Indications for Use *(Describe)*
The ScanX Edge is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.

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 K202633

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Date Summary Prepared: August 14, 2020

1. Submitter's Identification:

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2. Device Name:
   Trade /Proprietary Name: ScanX Edge
   Regulation Number: 21 CFR 872.1800
   Regulation Name: Extraoral source x-ray system
   Regulatory Class: II
   Product Code: MUH

3. Legally Marketed Predicate Device Information:
   Trade/Device Name: ScanX Intraoral View K170733
   Regulation Number: 21 CFR 872.1800
   Regulation Name: Extraoral source x-ray system
   Regulatory Class: II
   Product Code: MUH

4. Device Description:

The ScanX Edge is a dental device that scans photostimulable phosphor storage plates that have been exposed in place of dental X- Ray film and allows the resulting images to be displayed on a personal computer monitor and stored for later recovery. It will be used by licensed clinicians and authorized technicians for this purpose. The device is an intraoral Plate Scanner, which is designed to read out intraoral Plates of the sizes 0, 1 and 2. intraoral plate Scanners are state of the art since 2002 and are available in various designs from many companies around the world. The intraoral Plates are put into the mouth of the patient, exposed to X-rays and then are read out with the device. The read-out-process is carried out with a 635nm Laser. The laser beam is moved across the surface of the plate by an oscillating MEMS mirror. The laser beam stimulates the top coating of the plates, which consists of x-ray sensitive material. Depending on the exposed dose, the coating emits different levels of light. These light particles are then requisitioned by an optical sensor (Photo Multiplier Tube/ PMT) and transferred into an electrical output signal. This signal is digitalized and is the data for the digital X-ray image. The data is transmitted via an Ethernet link to a computer. Before the plate is discharged, the remaining data is erased by a LED-PCB. The user chooses which size of plate he has to use and prepares the device by inserting the appropriate plate insert into the device. He then exposes the plate and then puts the plate directly into the insert by pushing it out of the light protection envelope. The user closes the light protection cover and starts the read out process. After the read out process the picture is transmitted to the connected PC, the picture can be viewed and the IP is erased and ready to use for the next acquisition.

5. Intended Use/Indications for use:

The ScanX Edge is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.

6. Safety and Effectiveness:

The Edge is a device that scans photostimulable phosphor storage plates that have been exposed in place of x-ray film and allows the resulting images to be displayed on a personal computer monitor. Safety concerns associated with the ScanX Edge were addressed by safety testing the device with Intertek to IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 +A1:2012 (Electrical Safety), IEC 60601-1-2:2014 (EMC) and IEC 60825-1 second edition (Laser safety). Design changes and risks associated with the introduction of the ScanX Edge were properly mitigated by DÜRR Dental's cGMP compliant Quality Management System, change control processes, risk assessments, and product validation.
The ScanX Edge contains a Class 1 Laser Device as defined by 21 CFR 1040.10
The ScanX Edge is a non-patient contact Class II medical device.

7. Substantial Equivalence to Predicate Device Summary

DÜRR Dental's ScanX Edge is identical in function, and intended use to the DÜRR Dental ScanX Intraoral View K170733. Both units capture, digitize, and process intraoral x-ray images that are stored in imaging plate recording media.

8. Table of comparison to Legally Marketed Device:

Descriptive Information:	Predicate Device: ScanX Intraoral View as cleared via 510(k) K170733	Subject Device: ScanX Edge	Change Impact Analysis:
Device Photo			Different look, same functionalities.
Indications for Use	The ScanX Intraoral View is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.	The ScanX Edge is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.	No change.
Mechanical design	The exposed and unwrapped plates are scanned in two orthogonal directions using a laser with a wavelength of approximately 650 nm.	The exposed and unwrapped plates are scanned using a laser with a wavelength of 650nm. The scan pattern is not line by line but follows a certain geometrical figure.	Similar technology. The *ScanX Edge* shows different constructive solutions for the performance itself, without influencing the intended use or safety. The operating principle is still the same. The image plates are scanned by a laser light.
Electrical design	Light with a wavelength of approximately 380 nm is from the plate in proportion to the number of captured x-ray photons. This light is collected and formed into an image that may be viewed on a video display and stored for later recovery in a computer memory.	Same principle.	Slightly different implementation. The difference lies within the used laser diode. The diode used in the *ScanX Edge* is a fiber pigtailed diode and the one used in the *ScanX Intraoral View* is a standard diode. Both have identical specifications concerning the wavelength.

Descriptive Information:	Predicate Device: ScanX Intraoral View as cleared via 510(k) K170733	Subject Device: ScanX Edge	Change Impact Analysis:
Image scanning	Laser / Photomultiplier Tube. Components : PHOTOMULTIPLIER 5 » HAMAMATSU (Part-No. : 2151-150-50) DIODE, LASER- 635nm/15mW TO9 (Art-Nr.: 9135-80-002)	Laser / Photomultiplier Tube Components : Photomultiplier 2 » Hamamatsu (Part-Nr. : 2160-100189) Diode, Laser 639nm/10mW Pigtail (Art-Nr. : 9135100003)	No change: A laser and photomultiplier tube (PMT) is used for image scanning. Different components are used. The *ScanX Edge* has a different Laser Module and PMT Module. The diode used in the *ScanX Edge* is a fiber pigtailed diode and the one used in the *ScanX Intraoral View* is a standard diode.
Erasing the residual image following scanning for plate reuse	The residual image is erased in the scanner by an inline erasing function.	The residual image is erased in the scanner by an inline erasing function.	No change.
Viewing the image	4.3" Touch Screen. The touch screen only shows a preview which serves to provide an initial impression of the final x-ray image. For the purposes of diagnosis, the x-ray image must be viewed on a diagnostic monitor. The scanned images are displayed on an internal LCD or an external monitor using a computer and user software including image storage, retrieval and manipulation.	The ScanX Edge does not have a screen.	Different. The *ScanX Edge* does not have a screen. This difference does not influence the intended use for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.
Transport / feed mechanism	The plates are transported by "beltways" down the axis of the cylinder past the slot. The motion of the laser and plates provides the two orthogonal scan directions. This is a continuous feed device that allows successive plates to be loaded as soon as the previous plates have moved past the slot.	The plates are inserted into a size specific interchangeable insert. If the user wants to scan a different plate size, the insert needs to be exchanged. The insert is used to transport the plate into the scanning position. During the scanning process the plate is not move. Upon completion of the scanning process the plate is moved towards the discharging position Afterwards the	Different. The *ScanX Edge* shows different constructive solutions for the performance itself, without influencing the intended use or safety. The operating principle is still the same by means of that the image plate is transported in the scan position. After the scanning procedure the image plate is ejected from the device.

Descriptive Information:	Predicate Device: ScanX Intraoral View as cleared via 510(k) K170733	Subject Device: ScanX Edge	Change Impact Analysis:
		plate is ejected from the device.	
Plates to be used with the device	Dental intraoral Size 0: 22 x 35 mm Size 1: 24 x 40 mm Size 2: 31 x 41 mm Size 3: 27 x 54 mm Size 4: 57 x 76 mm	Dental Intraoral Size 0: 22 x 35 mm Size 1: 24 x 40 mm Size 2: 31 x 41 mm	Similar. The *ScanX Edge* is used with the smaller phosphor plates only: Size 0, 1 and 2. The phosphor plate sizes are within the *Intended Use* as defined by the predicate device.
Image quality	Theoretical resolutions: 10, 20, 25 or 40 LP/mm	Max. theoretical resolution Approx.. 16.7 Lp/mm	Similar.
MTF	More than 45% at 3 lp/mm	More than 40% at 3 LP/mm	Similar. The measurement was done on the basis of IEC 62220-1 with minor deviations due to the dental application of the radiography device. The lower DQE did not adversely affect image quality as shown by our SSD testing.
DQE	More than 7.5% at 3 lp/mm	More than 3,4% at 3 LP/mm	
Image data bit depth	16 bits	16 bits	No change.
Product size and weight	380 x 410 x 450 [mm]; (W x L x H) 19.5 [kg] (42.99 lbs.)	167x231x216 (W x L x H) Approx. 4 Kg (8,82 lbs.)	Different. No impact on safety/effectiveness.
Imaging Software	• DBSWIN/VistaEasy	• DBSWIN/VistaEasy, K190629 • VisionX K192743	The *ScanX Edge* can be used with the imaging software DBSWIN and VisionX.
Energy Source AC	100 to 240VAC, 50/60 Hz	100 to 240VAC, 50/60 Hz	No change.
Patient Contamination prevention	Single patient use barrier envelope encloses the imaging plate while in the patient's mouth.	Single patient use barrier envelope encloses the imaging plate while in the patient's mouth.	No change. (Cleared in K190949)

Descriptive Information:	Predicate Device: ScanX Intraoral View as cleared via 510(k) K170733	Subject Device: ScanX Edge	Change Impact Analysis:
RFID	The ScanX Intraoral View does not support the RFID function	The ScanX Edge supports image plates with RFID Tags. The RFID tag is programmed with the following information: - Brandname DD, AT, OEM. - HIBC - Date of production - Type of image plate	Different. The RFID performance has no influence on the intended use or safety of the device. The information on the RFID Tag is used to identify the image plate as a specific plate.
Electronic User Manual	User manual is provided in printed form to the user.	The user manual is provided in electronic form to the user.	Different. In accordance with the FDA Guidance "*Acceptable Media for electronic Product User Manuals*" issued on 18 March 2010, the user manual can be provided in electronic form only. No additional storage medium (DVD, or USB-Stick) will be provided. The user manual can be downloaded from the website of Air Techniques. Paper copies will be provided upon request.
Standards Compliance	US Performance Standard for Lasers **21CFR1040** **IEC 60825-1** Edition 2.0 2007-03, safety of laser products - part I: equipment classification, and requirements **IEC 61010-1** :2010 (Third Edition), Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 1: General Requirements **EN 61326-1** :2013, Electrical Equipment for Measurement, Control and Laboratory Use, EMC requirements	US Performance Standard for Lasers **21CFR1040** **IEC 60825-1** - TEST REPORT Safety of laser products - Part 1: Equipment classification and requirements **IEC 60601-1** Medical electrical equipment Part 1: General requirements for basic safety and essential performance **IEC 60601-1-2**:2014, EN 60601-1-2:2015 EMC Professional healthcare facility environment / Emission class B)	Standards chosen are more suitable for use in the healthcare environment

The technological characteristics, including design, materials, composition, and energy source, are substantially the same, so there are no issues impacting safety and effectiveness.

9. Summary of non-clinical performance testing:
   Risk analysis and software validation was successfully performed. Cybersecurity issues were addressed by observance of the recommendations in the FDA Guidance *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014*

This device meets the applicable portions of the following international standards:

IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2014, (Professional healthcare facility environment / Emission class B) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

IEC-60825-1 Safety of laser products - Part 1: Equipment classification and requirements Ed.2. The laser aspects of this device comply with the US Performance Radiation Safety Standard in 21CFR1040.

MTF and DQE image performance testing was performed with reference to IEC 62220-1:2003. Noise power spectrum measurements were documented. The following FDA Guidance Document was consulted during the development of this device: *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices, Guidance for Industry and Food and Drug Administration Staff, Document issued on: September 1, 2016.*

The development of labeling was done in accordance with the FDA Guidance *Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff Document issued on November 28, 2017.* Because the modified unit employs RFID, we also consulted the FDA Guidance *Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document issued on: August 14, 2013*

10. Summary of clinical performance testing:
    Not required to establish substantial equivalence.

11. Conclusion: In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, DÜRR Dental SE concludes that the ScanX Edge is safe and effective and substantially equivalent to the predicate device as described herein.