February 6, 2023

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

Re: K230095
Trade/Device Name: ScanX Swift 2.0, ScanX Swift View 2.0
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: January 9, 2023
Received: January 12, 2023

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,

Lu Jiang 2023.02.06 16:03:19 -05'00'

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)*
K230095

Device Name
ScanX Swift 2.0, ScanX Swift View 2.0

Indications for Use *(Describe)*
The ScanX Swift 2.0 is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.

The ScanX Swift View 2.0 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.

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510(k) Summary, DURR DENTAL SE K230095

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: January 25, 2023

1. Submitter's Identification:

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2. Device Name:

Trade /Proprietary Name:	ScanX Swift 2.0, ScanX Swift View 2.0
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:	K202633, ScanX Edge
Regulation Number:	21 CFR 872.1800
Regulation Name:	Extraoral source x-ray system
Regulatory Class:	II
Product Code:	MUH

4. Device Description:
   The ScanX Swift 2.0 and ScanX Swift View 2.0 are dental devices that scan 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 all cleared plates of the sizes 0, 1, 2, 3, and 4. The phosphor plates are made of rigid photostimulable material. Intraoral phosphor plate x-ray (also known as phosphor storage plate or PSP x-ray) eliminates the need for traditional film processing for dental radiography. Phosphor storage plates can convert existing film based imaging systems to a digital format that can be integrated into a computer or network system. 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 639nm 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. The main difference between the two models is on the ScanX Swift View 2.0 the display is larger, has touch capability, and can show a preview of the scan image. The device firmware is based on the predicate firmware and is of a moderate level of concern.

5. Indications for use: (Identical for two models, same as predicate)
   The ScanX Swift 2.0 is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.
   The ScanX Swift View 2.0 is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.

6. Summary of the technological characteristics of the device compared to the predicate device:
   The ScanX Swift 2.0 / ScanX Swift View 2.0 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 Swift 2.0 / ScanX Swift View 2.0 were addressed by safety testing the device according to recognized consensus standards as listed in the section below: “List of Applied Standards”. Design changes and risks associated with the introduction of the ScanX Swift 2.0 / ScanX Swift View 2.0 were properly mitigated by DURR DENTAL SE’s cGMP compliant Quality Management System, change control processes, risk assessments, and product validation. The ScanX Swift 2.0 / ScanX Swift View 2.0 contains a Class 1 Laser Device as defined by 21 CFR 1040.10. The modified units employ RFID in the same manner as the predicate. Installation and operation manuals are provided with instructions for safe use and servicing of the ScanX Swift 2.0 / ScanX Swift View 2.0. The ScanX Swift 2.0 / ScanX Swift View 2.0 is a non-patient contact Class II medical device.

7. Equivalence to Predicate Device Summary:
   DURR DENTAL SE’s ScanX Swift 2.0 / ScanX Swift View 2.0 units are identical in function, and intended use to the DURR DENTAL SE ScanX Edge K202633. All three units capture, digitize, and process intraoral x-ray images that are stored in imaging plate recording media. The technological characteristics, including design, materials, composition, and energy source, are substantially the same, so there are no issues impacting safety and effectiveness. Both units have the convenience of RFID capability. The main difference is the addition of compatible plate sizes: Size 3: 27 x 54 mm and Size 4: 57 x 76 mm. Refer to the substantial equivalence comparison table below..

Device	Predicate device	Subject devices		Change Impact Analysis
Trade name	**ScanX Edge**	**ScanX Swift 2.0**	**ScanX Swift View 2.0**	---
Model Name	ScanX Edge	XPS07.1A1	XPS07.2A1	---
Clearance	K202633	---	---	---
Device Picture				Different.
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.**	**The ScanX Swift 2.0 is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.**	**The ScanX Swift View 2.0 is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.**	**Identical.**
Technical equivalence:				
Operating principle	**The PSPs 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 639 nm Laser. 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 and transferred into an electrical output signal. This signal is digitalized and is the data for the digital X-ray image.**	**The PSPs 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 639 nm Laser. 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 and transferred into an electrical output signal. This signal is digitalized and is the data for the digital X-ray image.**		Identical.

Device	Predicate device	Subject devices		Change Impact Analysis
Data transfer	The data is transmitted via an Ethernet link.	The data is transmitted via an Ethernet link to a computer. With the XPS07.2A1 the data can alternatively be transferred by a WLAN interface or being stored on a removeable storage medium.		Similar.
Erasing the residual image following scanning for plate reuse	After the scanning process, the remaining data is erased by a LED light.	After the scanning process, the remaining data is erased by a LED light.		Identical.
Display	The ScanX Edge does not have a screen / display. The device state is indicated via status LEDs lights on the device.	2.4''-Display The display does not show preview images.	5''-Touch Display: 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 PC monitor. Diagnostic monitor = PC monitor. The scanner itself is not used for diagnosis.	Similar.
Imaging scanning	Laser / Photomultiplier Tube (PMT) Components: Photomultiplier 2" Diode, Laser 639nm/10mW Fiber coupled laser diode	Laser / Photomultiplier Tube (PMT) Components: Photomultiplier 2" Diode, Laser 639nm/10mW Fiber coupled laser diode		Identical.
Plate guide	A specific plate guide for each PSP size is available, thus the user chooses which size of PSP he wants to use and prepares the device by inserting the appropriate plate guide into the device.	A specific plate guide for each PSP size is available, thus the user chooses which size of PSP he wants to use and prepares the device by inserting the appropriate plate guide into the device.		Identical.

Device	Predicate device	Subject devices		Change Impact Analysis
Transport / feed mechanism	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.	The plates are inserted into a size specific interchangeable plate guide. If the user wants to scan a different plate size, the plate guide needs to be exchanged. The plate is transported beltway 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.		Similar. The solutions for the plate guides have evolved for ScanX Swift 2.0 and ScanX Swift View 2.0. The feed and transport are equivalent.
WLAN (Wi-Fi)	No	No	Yes	Different. Added interface flexibility
Ethernet	Yes	Yes	Yes	SAME
RFID	Supports image plates with RFID Tags. The information on the RFID tag is used to identify the image plate.	Supports image plates with RFID Tags. The information on the RFID tag is used to identify the image plate.	Supports image plates with RFID Tags. The information on the RFID tag is used to identify the image plate.	Identical. The RFID image plates are identical.

Device	Predicate device	Subject devices		Change Impact Analysis
Operation / Function	The image plate scanner is used to read image data stored on an image plate and to transfer the data to the imaging software (e.g. VisionX) on a computer. The transport mechanism guides the image plate through the device. The image plate is read using a laser inside the scanner unit. The scanned data is converted into a digital image and transferred to the imaging software. After scanning, the image plate runs through the erasure unit. Image data still held on the image plate is erased with the aid of bright light. The image plate is then ejected for re-use.	The phosphor storage plate scanner is used to scan image data stored on a phosphor storage plate and transfer the data to the imaging software (e.g. VisionX) on a computer. The transport mechanism guides the phosphor storage plate through the device. The phosphor storage plate is read using a laser inside the scanner unit. The scanned data is converted into a digital image and transferred to the imaging software. After scanning, the phosphor storage plate runs through the erasure unit. Image data still held on the phosphor storage plate is erased with the aid of bright light. The phosphor storage plate is then ejected for re-use.	The phosphor storage plate scanner is used to read image data stored on the phosphor storage plate. The unit can be used in two different ways: via the imaging software (e. g. VisionX) on a PC or directly via the touch screen on the unit. The transport mechanism guides the phosphor storage plate through the device. A laser in the scanner unit scans the PSP. The scanned data is converted into a digital image. If a scanning job is started via the imaging software, the image is automatically transmitted to the computer. If a scanning job is started via the touch screen, the image is saved to the memory card and needs to be transferred to the computer later on. After scanning, the phosphor storage plate runs through the erasure unit. Image data still held on the phosphor storage plate is erased with the aid of bright light. The phosphor storage plate is then ejected for re-use.	Identical. Different: **ScanX Swift View 2.0:** The touch screen allows the unit to be operated in a stand-alone mode (without a connection to a computer). The device is able to generate the image data itself and to store it on a data medium (USB stick). Instructions can be entered on the touch screen with the tip of a finger.
Phosphor storage plates	Only AT Phosphor Storage Plates with RFID tag: Size 0: 22 x 35 mm Size 1: 24 x 40 mm Size 2: 31 x 41 mm	Only AT Phosphor Storage Plates with RFID tag: 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		Similar. The predicate device uses the smaller phosphor plates: Size 0, 1 and 2.

Device	Predicate device	Subject devices		Change Impact Analysis
Max. theoretical resolution (Line pairs/mm)	Approx. 40 Lp/mm	Approx. 40 Lp/mm		SAME.
MTF	More than 40% at 3 LP/mm	Horizontal 59% Vertical 49% at 3LP/mm in 12.5µm pixel size mode		Similar/better.
DQE	More than 3,4% at 3 LP/mm	Horizontal 8.5%, Vertical 10.5% at 3LP/mm in 12.5µm pixel size mode with an exposure of 99µGy		Similar/better.
Image bit depth	16 bits	16 bits		Identical.
Dimensions (mm) (W x H x D)	167 x 244 x 216	211 x 249 x 258	211 x 273 x 258	Different.
Weight	Approx. 4 kg (8,82 lb)	Approx. 5,1 kg (11,24 lb)	Approx. 5,3 kg (11,68 lb)	Different.
Energy Source AC	100 to 240VAC, 50/60 Hz	100 to 240VAC, 50/60 Hz	100 to 240VAC, 50/60 Hz	Identical.
Imaging Software	• DBSWIN (K203287) • VisionX (K213326)	• VisionX (K213326)	• VisionX (K213326)	Different. The predicate can be used with *DBSWIN* or *VisionX* imaging software, whereas the subject devices exclusively used with the *VisionX* imaging software.
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.	Single patient use barrier envelope encloses the imaging plate while in the patient's mouth.	Identical.
Additional Features	None.	• Flip-side detection	• Stand-Alone-Mode • Flip-side detection • SmartScan Workflow: **ScanX Smart Reader**	Different. The **ScanX Smart Reader** is a new accessory which is included in the scope of delivery of the subject device **ScanX Swift View 2.0**.

Discussion of Similarities and Differences:

1) **Interface between the subject devices and the imaging software (VisionX):**
   New: The image generation originates on the image plate scanner side of the software- hardware interface. Previously the image was assembled by the imaging software (e.g. VisionX). As a novelty, the composition of the image now takes place within the image plate scanner. The raw image data used to assemble the image is the same. The algorithm used for this process is the same as cleared in K192743 for the imaging software VisionX.

2) **Smart Scan Workflow:**
   The **ScanX Smart Reader** is a new accessory which is included in the scope of delivery of the subject device **ScanX Swift View 2.0**. The ScanX Smart Reader is not a medical device. The unit is able to read RFID chips from different sources. Using the ScanX Smart Reader it is possible to assign IQ image plates to a patient. The images are then automatically assigned to this patient when they are scanned.

3) **Stand-Alone Modus:**
   ScanX Swift View 2.0: The touch screen allows the unit to be operated in a stand-alone modus, without a connection to a computer. The device is able to generate the image data itself and to store it on a data medium (USB stick). Instructions can be entered on the touch screen with the tip of a finger.

4) **Wifi**
   Applicable for **ScanX Swift View 2.0** only. All models support Ethernet connection to the host computer.

5) **Display/ Screen:**
   The subject devices have displays. The **ScanX Swift View 2.0** does have a touch screen, which allows the unit to be operated in a stand-alone modus. The predicate device **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.

6) **Technology:**
   The feeding and scanning process are different.

   - The predicate device ScanX Edge uses the **MEMS technology**: MEMS = Micro Electro Mechanical Systems.
   - The subject devices ScanX Swift 2.0 and ScanX Swift View 2.0 use the **Flying-Spot configuration** (PCS technology): PCS = Photo Collecting Systems. This technology was already cleared for a predecessor device ScanX Intraoral View (IO View), in K170733.

7) **Image Plate Sizes:**
   - The modified ScanX models allow the use of previously cleared larger plate sizes. These larger sizes were available on our previous model ScanX cleared in K170733.

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

8. 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
   The following FDA guidance documents were consulted during the development of this device:
   FDA Guidance "Pediatric Information for X-ray Imaging Device Premarket Notifications"
   FDA Guidance "Radio Frequency Wireless Technology in Medical Devices."
   FDA Guidance "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices,.

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

   IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 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, DQE, and image resolution performance testing was performed in accordance with IEC 62220-1:2003. The results were measured values, not theoretical. 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,*
   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.* 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.*

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

10. 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 Swift 2.0, ScanX Swift View 2.0 models are safe and effective and substantially equivalent to the predicate device as described herein.