DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2017

Duerr Dental AG
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

Re: K170733
Trade/Device Name: ScanX Intraoral View
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: January 30, 2017
Received: March 10, 2017

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170733

Device Name
ScanX Intraoral View

Indications for Use *(Describe)*
The ScanX Intraoral View 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.

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

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Exhibit 5. 510(k) SUMMARY

510(k) Summary, DUERR DENTAL AG, K170733

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

1. Date Summary Prepared:

April 12, 2017

2. Submitter's Identification:

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3. Device Name:

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

4. Legally Marketed Predicate Device Information:

Trade/Device Name: RIOScan (RPS500) Manufactured by RAY Co., Ltd.
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH

5. Device Description:

The ScanX Intraoral View 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.

6. Intended Use/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.

7. Safety and Effectiveness:

The ScanX Intraoral View 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 Intraoral View were addressed by safety testing the device with Intertek to IEC 61010-1 third edition (Electrical Safety), EN 61326-1:2013 (EMC) and IEC 60825-1 second edition (Laser safety). Design changes and risks associated with the introduction of the ScanX Intraoral View were properly mitigated by Duerr Dental's cGMP compliant Quality Management System, change control processes, risk assessments, and product validation.

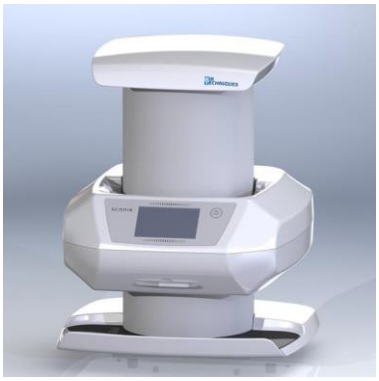
The ScanX Intraoral View contains a Class 1 Laser Device as defined by 21 CFR 1040.10

Installation and operation manuals are provided with instructions for safe use and servicing of the ScanX Intraoral View. The ScanX Intraoral View is a non-patient contact Class II medical device.

8. Substantial Equivalence to Predicate Device Summary

Duerr Dental's ScanX Intraoral View is identical in function, and intended use to the RIOScan RPS500 Dental Radiography System manufactured by RAY Co., Ltd whose dental units are in commercial distribution and are FDA cleared under 510K # K160788.
ScanX Intraoral View and the RIOScan RPS500 capture, digitize, and process intraoral x-ray images that are stored in imaging plate recording media.

9. Table of comparison to Legally Marketed Device:

Comparison criteria	Predicate Device: RIOScan RPS500 K160788, RAY Co. Ltd.	New Device ScanX Intraoral View
Photo		
Indications for Use	This system is a digital intraoral dental radiographic imaging system intended for use by dentists and dental sub-specialists. The system captures, digitizes, displays and stores diagnostic intraoral radiographic images.	The ScanX Intraoral View is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.
Mechanical design	The exposed and unwrapped plates are scanned using a laser with a certain wavelength.	The exposed and unwrapped plates are scanned in two orthogonal directions using a laser with a wavelength of approximately 650 nm.
Electrical design	Light with a certain wavelength 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 and stored on an external display/computer.	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.
Image scanning	Laser/Photomultiplier Tube	SAME
Erasing the residual image following scanning for plate reuse.	Automatic plate erasing	The residual image is erased in the scanner by an inline erasing function.

Comparison criteria	Predicate Device: RIOScan RPS500 K160788, RAY Co. Ltd.	New Device ScanX Intraoral View
Viewing the image	The scanned images can be displayed on an integrated LCD panel, a 4.3" Touch Screen	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.
Transport/feed mechanism	Gravity scan	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.
Phosphor Plates	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	Same as predicate device.
Image Quality	Theoretical resolutions: 9, 16, or 21 lp/mm	Theoretical resolutions: 10, 20, 25 or 40 LP/mm
MTF	More than 35% at 3 lp/mm	More than 45% at 3 lp/mm
DQE	More than 10% at 3 lp/mm	More than 7.5% at 3 lp/mm
Image data bit depth	14 bits	16 bits
Body size and weight	170 x 260 x 278 [mm]; 3.6 [kg]	380 x 410 x 450 [mm]; (W x L x H) 19.5 [kg] (42.99 lbs.)
Imaging Software	"RIOView"	DBSWIN/VistaEasy as cleared in K161444
User interface	It will be used by dentists and authorized dental auxiliary personnel.	Same as predicate device.
Energy Source AC	100 to 240VAC, 50/60 Hz,	Same as predicate device.

Comparison criteria	Predicate Device: RIOScan RPS500 K160788, RAY Co. Ltd.	New Device ScanX Intraoral View
Electrical safety standards	IEC 60601-1 Electrical Safety Medical Devices	EN 61010-1:2010 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
EMC Testing	IEC 60601-1-2 EMC Medical Devices	EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements
Patient Contamination prevention	Single patient use barrier envelope encloses the imaging plate while in the patient's mouth.	Same as predicate device

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

10. Summary of non-clinical performance testing:

Risk analysis and software validation was successfully performed. EMC Testing according to EN 61326-1:2013 was successfully performed. Electrical safety testing according to EN 61010-1:2010 was successfully performed. We chose safety standards that were more closely aligned with where the device is to be used: Equipment for Measurement, Control, and Laboratory Use.
FDA guidance documents utilized in the development of the device:
a) Imaging performance evaluation according to the recommendations in the FDA guidance document: *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Document issued on: September 1, 2016*.
b) Software development: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*
c) Cybersecurity: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.*
MTF and DQE image performance testing was performed with reference to IEC 62220-1:2003. Noise power spectrum measurements were documented.

11. Summary of clinical performance testing:

Not required to establish substantial equivalence.

12. <u>Conclusion</u>

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Duerr Dental AG concludes that the ScanX Intraoral View is safe and effective and substantially equivalent to the predicate device as described herein.