November 2, 2021

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

Re: K213326
Trade/Device Name: VisionX 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 1, 2021
Received: October 5, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213326

Device Name
VisionX 3.0

Indications for Use *(Describe)*

The software is intended for the viewing and diagnosis of image data in relation to dental issues. Its proper use is documented in the operating instructions of the corresponding image-generating systems. Image-generating systems that can be used with the software include optical video cameras, digital X-ray cameras, image plate scanners, extraoral X-ray devices, intraoral scanners and TWAIN compatible image sources.

The software must only be used by authorized healthcare professionals in dental areas for the following tasks:
- Filter optimisation of the display of 2D and 3D images for improved diagnosis
- Acquisition, storage, management, display, analysis, editing and supporting diagnosis of digital/digitised 2D and 3D images and videos
- Forwarding of images and additional data to external software (third-party software)

The software is not intended for mammography use.

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, DÜRR DENTAL SE,
Device Name: VisionX 3.0
K213326

This 510(k) is being submitted in accordance with the requirements of 21 CFR §807.92.

1. Submitter

Submitter:	**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	Establishment Registration Name in FURLS: **Duerr DENTAL SE**
Establishment Registration Number:	3015509619	
Contact Person:	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	

Date summary prepared: Thursday, September 30, 2021

2. Device:

Trade /Proprietary Name:	VisionX 3.0
Device:	Medical Imaging Software
Regulation Description:	Medical image management and processing system.
Regulation Medical Specialty:	Radiology
Review Panel	Radiology
Product Code	LLZ
Regulation Number	892.2050
Device Class	2

3. Predicate Device:

Legally Marketed Predicate Device Information:

510(k) Number:	K192743
Manufacturer:	DÜRR DENTAL SE
Trade /Proprietary Name	VisionX 2.4

Device:	Medical Imaging Software
Regulation Description:	Medical image management and processing system.
Regulation Medical Specialty:	Radiology
Review Panel	Radiology
Product Code	LLZ
Regulation Number	892.2050
Device Class	2

4. Device Description:

VisionX 3.0 imaging software is an image management system that allows dentists to acquire, display, edit, view, store, print, and distribute medical images. VisionX 3.0 software runs on user provided PC-compatible computers and utilize previously cleared digital image capture devices for image acquisition.

5. Indications for Use

The software is intended for the viewing and diagnosis of image data in relation to dental issues. Its proper use is documented in the operating instructions of the corresponding image-generating systems. Image-generating systems that can be used with the software include optical video cameras, digital X-ray cameras, image plate scanners, extraoral X-ray devices, intraoral scanners and TWAIN compatible image sources.

The software must only be used by authorized healthcare professionals in dental areas for the following tasks:

- Filter optimization of the display of 2D and 3D images for improved diagnosis
- Acquisition, storage, management, display, analysis, editing and supporting diagnosis of digital/digitized 2D and 3D images and videos
- Forwarding of images and additional data to external software (third-party software)

The software is not intended for mammography use.

6. Comparison of technological characteristics with the predicate device

VisionX 3.0 represents these enhancements as compared to our predicate:

- Automatic nerve canal calculation
- Automatic imaging plate quality check
- Improved 3D panoramic display
- VisionX Connect
- Automatic image rotation
- User management

A detailed comparison table is provided on the next page.

	VisionX 2.4 K192743	VisionX 3.0	Evaluation
Manufacturer	**DÜRR DENTAL SE**	**DÜRR DENTAL SE**	Identical
Clinical:			
Indications for use	The software is intended for the viewing and diagnosis of image data in relation to dental issues. Its proper use is documented in the operating instructions of the corresponding image-generating systems. Image generating systems that can be used with the software include optical video cameras, digital X-ray cameras, image plate scanners, extraoral X-ray devices, intraoral scanners and TWAIN compatible image sources. The software must only be used by authorized healthcare professionals in dental areas for the following tasks: - Filter optimization of the display of 2D and 3D images for improved diagnosis - Acquisition, storage, management, display, analysis, editing and supporting diagnosis of digital/digitized 2D and 3D images and videos - Forwarding of images and additional data to external software (third-party software) The software is not intended for mammography use.	The software is intended for the viewing and diagnosis of image data in relation to dental issues. Its proper use is documented in the operating instructions of the corresponding image-generating systems. Image-generating systems that can be used with the software include optical video cameras, digital X-ray cameras, image plate scanners, extraoral X-ray devices, intraoral scanners and TWAIN compatible image sources. The software must only be used by authorized healthcare professionals in dental areas for the following tasks: - Filter optimization of the display of 2D and 3D images for improved diagnosis - Acquisition, storage, management, display, analysis, editing and supporting diagnosis of digital/digitized 2D and 3D images and videos - Forwarding of images and additional data to external software (third-party software) The software is not intended for mammography use.	Identical
Specifications:			
Functions	- Imaging application including a viewer and job interface - Viewer - Test module - Implant visualization - 3D imaging module - Layouts (structured displays) - DICOM-Workflow (RIS & PACS)	- Imaging application including a viewer and job interface - Image viewer - Inspect test module - Implant visualization - 3D imaging module - Layouts (structured displays) - DICOM-Workflow (RIS & PACS & Print) - User management - Automatic rotation (AI) - Automatic nerve canal tracing (AI) - In-line automatic image plate quality checks (AI) - Improved panoramic curve detection (AI) - VistaSoft/VisionX Connect to integrate Dürr Dental and Air Techniques devices into 3rd party software	New functions were added
Patient Management	Yes	Yes	Identical

	VisionX 2.4 K192743	VisionX 3.0	Evaluation
Manufacturer	**DÜRR DENTAL SE**	**DÜRR DENTAL SE**	Identical
Image Management	Yes	Yes	Identical
Acquisition sources X-ray (i.e. Phosphor Plate, Digital Panoramic) Laser Fluorescence Caries Detection Aid	 Yes Yes	 Yes Yes	Identical
Display images	Yes	Yes	
Safe/Store images	Yes	Yes	
Produce reports	Yes	Yes	
Enhance images Brightness Contrast Crop Rotate Zoom in/out Invert Sharpen Measure Annotate	 Yes Yes Yes Yes Yes Yes Yes Yes Yes	 Yes Yes Yes Yes Yes Yes Yes Yes Yes	
Run on standard PC compatible computers	Yes	Yes	Identical
Computer operating systems	Microsoft Windows 7 Microsoft Windows 8.1 Microsoft Windows 10 Microsoft Windows Server 2016 Microsoft Windows Server 2019	64-bit operating system: Microsoft Windows 8.1 (not Windows RT) Microsoft Windows 10 (Pro or higher) Microsoft Windows Server 2016 Microsoft Windows Server 2019	Identical (except of Windows 7, which is no longer supported by Microsoft)
Supportive devices	- ScanX - ProVecta S-Pan - ProVecta 3D - CamX	- ScanX - ProVecta S-Pan - ProVecta 3D - CamX - SensorX	Added Device: SensorX (K203116)
System requirements:			
CPU	≥ Intel Core i3	≥ Intel Core i3	Identical
RAM	≥ 4 GB	≥ 4 GB For automatic nerve canal detection: ≥ 8 GB	Similar
Drive	DVD ROM	USB, DVD-ROM or download	Similar
Hard disk	Workstation (without database) ≥ 50 GB The database memory requirements depend on the number of images taken at the surgery in question. (Camera image: approx. 1 MB, X-ray image: approx. 2 MB – 10 MB, CBCT: 200 – 300 MB)	Workstation (without database) ≥ 50 GB The database memory requirements depend on the number of images taken at the surgery in question. (Camera image: approx. 1 MB, X-ray image: approx. 2 MB - 10 MB, CBCT: 200 - 300 MB)	Identical
Data backup	Daily data back-up	Daily data back-up	Identical
Interface	Ethernet ≥ 100 Mbit	Ethernet ≥ 100 Mbit/s	Identical

	VisionX 2.4 K192743	VisionX 3.0	Evaluation
Manufacturer	**DÜRR DENTAL SE**	**DÜRR DENTAL SE**	Identical
Diagnostic Monitor	In accordance with DIN 6868-157, room category 5 or 6 (depending on the requirements)	In accordance with DIN 6868-157, room category 5 or 6 (depending on the requirements)	Identical
Resolution / graphics	Resolution ≥ 1280 x 1024 Depth of color 32-bit, 16.7 million colors Recommended for 3D X-ray images: NVIDIA GeForce 750 2 GB	Resolution ≥ 1280 x 1024 Depth of color 32-bit, 16.7 million colors For display of 3-D X-ray images: NVIDIA GeForce ≥ 1 GB For automatic nerve canal tracing: NVIDIA GeForce ≥ 4 GB	Similar

7. Non-Clinical Data and Performance Testing

VisionX 3.0 was developed in compliance with the harmonized standard of IEC 62304 for medical device software life cycle requirements.
Software testing, effectiveness, and functionality were successfully conducted and verified between VisionX 3.0 and image capture devices. Software was documented using the FDA guidance document "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" using a moderate level of concern. Cybersecurity was addressed according to the FDA guidance document "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff*."
VisionX 3.0 is DICOM compliant.
Risk Analysis based design development and design reviews were conducted.
Full functional software cross check testing was performed.

8. Clinical Data: Not required for a finding of substantial equivalence.

9. 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 VisionX 3.0 Imaging Software is substantially equivalent to the predicate device as described herein.

The device modifications to VisionX 3.0 do not alter the fundamental scientific technology of the predicate device and summary level information is adequate to assess the modifications. The verification testing demonstrates that the device continues to meet its performance specifications and the results of the testing did not raise new issues of safety or effectiveness. Therefore, the modified VisionX 3.0 can be found substantially equivalent to the predicate device as cleared in K192743.