Durr Dental SE
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, FLORIDA 34114

October 31, 2019

Re: K192743
Trade/Device Name: VisionX 2.4
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 26, 2019
Received: September 30, 2019

Dear Mr. Daniel 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)*
K192743

Device Name
VisionX 2.4

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 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.

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,

Device Name: VisionX 2.4

K192743

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

1. Date Summary Prepared:

September 19, 2019

2. Submitter's Identification:

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3. Device:

Trade /Proprietary Name:	VisionX 2.4
Device:	Medical Imaging Software
Regulation Description:	Picture archiving and communications system.
Regulation Medical Specialty:	Radiology
Review Panel	Radiology
Product Code	LLZ
Regulation Number	892.2050
Device Class	2

4. Predicate Device:

Legally Marketed Predicate Device Information:

510(k) Number:	K190629
Manufacturer:	DÜRR DENTAL SE
Trade /Proprietary Name	DBSWIN and VistaEasy Imaging Software
Device:	Medical Imaging Software
Regulation Description:	Picture archiving and communications system.
Regulation Medical Specialty:	Radiology
Review Panel	Radiology
Product Code	LLZ
Regulation Number	892.2050
Device Class	2

5. Device Description:

VisionX 2.4 imaging software is an image management system that allows dentists to acquire, display, edit, view, store, print, and distribute medical images. VisionX 2.4 software runs on user provided PC-compatible computers and utilizes previously cleared digital image capture devices for image acquisition. This software was cleared in K181432 as part of the x-Ray system ProVecta 3D Prime. With this submission VisionX will be established as standalone software. Additionally, new hardware was integrated: Support of the ScanX Touch / Duo Touch (K191623)

6. 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.

7. Summary of the technological characteristics of the device compared to the predicate device:

Comparison of the Technological Characteristics

Descriptive Information:	Predicate Device: DBSWIN and VistaEasy Imaging Software K190629	Subject Device: VisionX 2.4
Indications for Use	DBSWIN and VistaEasy imaging software are intended for use by qualified dental professionals for windows-based diagnostics. The software is a diagnostic aide for licensed radiologists, dentists and clinicians, who perform the actual diagnosis based on their training, qualification, and clinical experience. DBSWIN and VistaEasy are clinical software applications that receive images and data from various imaging sources (i.e., radiography devices and digital video capture devices) that are manufactured and distributed by DÜRR Dental and Air Techniques. It is intended to acquire, display, edit (i.e., resize, adjust contrast, etc.) and distribute images using standard PC hardware. In addition, DBSWIN enables the acquisition of still images from 3rd party TWAIN compliant imaging devices (e.g., generic image devices such as scanners) and the storage and printing of clinical exam data, while VistaEasy distributes the acquired images to 3rd party TWAIN compliant PACS systems for storage and printing. DBSWIN and VistaEasy software are 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.
Patient Management	Yes	Yes
Image Management	Yes	Yes
X-ray (i.e., Phosphor Plate, Digital Panoramic)	Yes	Yes
Laser Fluorescence Caries Detection Aid	Yes	Yes
Video	Yes	No

Photos	Yes	Yes
Documents	Yes	No
Import	Yes	Yes
Display Images	Yes	Yes
Save/Store Images	Yes	Yes
Produce Reports	Yes	Yes
Print/Export Images	Yes	Yes
Brightness	Yes	Yes
Contrast	Yes	Yes
Colorize	Yes	No
Crop	Yes	Yes
Rotate	Yes	Yes
Zoom In/Out	Yes	Yes
Invert	Yes	Yes
Sharpen	Yes	Yes
Measure	Yes	Yes
Annotate	Yes	Yes
Run on standard PC compatible computers	Yes	Yes
Operating Systems	Microsoft Windows 7, 32-bit (from Home to Premium) Microsoft Windows 7, 64-bit (from Home to Premium) Microsoft Windows 8.1, 64-bit Microsoft Windows 10, 64-bit Microsoft Windows Server 2012 Microsoft Windows Server 2016	Microsoft Windows 7, 64-bit Microsoft Windows 8.1, 64-bit Microsoft Windows 10, 64-bit Microsoft Windows Server 2016 Microsoft Windows Server 2019 Same but since Windows 7 is no longer supported by Microsoft we no longer recommend using this OS..
Supported Devices	Supported Device Families: • ScanX • ProVecta S-Pan • CamX	Supported Device Families: • ScanX • ProVecta S-Pan • CamX Added Device Family: • ProVecta 3D

8. Discussion of Similarities and Differences:

VisionX 2.4 represents these enhancements as compared to our predicate:

- VisionX as standalone software. Currently the VisionX is cleared as part of the System of ProVecta 3D prime only.
- 3D functionality: 3D images and videos for acquisition, storage, management, display, analysis, editing and supporting diagnosis of digital/digitized.
- Integration of the device family ProVecta 3D (x-ray system, cleared in K181432).
- Integration of new variants of image plate scanner of the "ScanX" device family.
- Integration of a new interface for an intraoral scanner.

9. Non-Clinical Data and Performance Testing

VisionX 2.4 was developed in compliance with the harmonized standard of IEC 62304 for medical device software life cycle requirements. We consulted this FDA guidance document during the software development: *Guidance for Industry and FDA Staff- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.
Software testing, effectiveness, and functionality were successfully conducted and verified between VisionX 2.4 and image capture devices. VisionX 2.4 is DICOM compliant.
Risk Analysis based design development and design reviews were conducted.
Full functional software cross check testing was performed.
Labeling and internal procedures have been updated to assure compliance with the FDA Guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices-Guidance for Industry and Food and Drug Administration Staff Document.*
In addition, we performed what we call a "Clinical Evaluation." This was an extensive detailed review of literature data, data from practical tests in dental practices, and safety data. It concluded that the software is suitable for an effective, efficient and safe dental use for the indications mentioned.

10. Clinical Data: 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 VisionX 2.4 Imaging Software is substantially equivalent to the predicate device as described herein. The device modifications to VisionX 2.4 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 2,4 can be found substantially equivalent to the predicate device as cleared in K190629.