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

November 18, 2020

Re: K203287
Trade/Device Name: DBSWIN and VISTAEASY Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 6, 2020
Received: November 9, 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 and Part 809); 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)*
K203287

Device Name
DBSWIN and VISTAEASY Imaging Software

Indications for Use *(Describe)*
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 Durr 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.

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,

DBSWIN and VISTAEASY Imaging Software

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

1. Date Summary Prepared:
November 12, 2020

K203287

2. Submitter's Identification:

Submitter's Identification:	**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 www.duerrdental.com	Establishment Registration Name in FURLS: **Duerr DENTAL SE**
Establishment Registration Number:	3015509619	
Submitter's Contact:	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	

3. Subject Device:

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

4. 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:

DBSWIN and VistaEasy imaging software is an image management system that allows dentists to acquire, display, edit, view, store, print, and distribute medical images. DBSWIN and VistaEasy software runs on user provided PC-compatible computers and utilize previously cleared digital image capture devices for image acquisition. VistaEasy is included as part of DBSWIN. It provides additional interfaces for Third Party Software. VistaEasy can also be used by itself, as a reduced feature version of DBSWIN.

6. 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 Duerr 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.

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

DBSWIN and VistaEasy imaging software by DÜRR DENTAL SE are two software components that are substantially equivalent to DBSWIN and VistaEasy Imaging Software K190629 software applications that have identical indications for use, functionality, performance, and features as shown in the following comparison Table.

8. Comparison of the Technological Characteristics

Descriptive Information	DBSWIN and VistaEasy Imaging Software K190629	DBSWIN and VistaEasy Imaging Software (Modified)
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 Duerr 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.	SAME, unchanged.
Patient Management	YES	YES
Image Management	YES	YES

Descriptive Information	DBSWIN and VistaEasy Imaging Software K190629	DBSWIN and VistaEasy Imaging Software (Modified)
Acquisition Sources		
X-ray (i.e., Phosphor Plate, Digital Panoramic)	YES	YES
Laser Fluorescence Caries Detection Aid	YES	YES
Video	YES	YES
Photos	YES	YES
Documents	YES	YES
Import*	YES	YES
Display Images	YES	YES
Safe/Store Images*	YES	YES
Produce Reports*	YES	YES
Print/Export Images*	YES	YES
Enhance Images		
Brightness	YES	YES
Contrast	YES	YES
Colorize*	YES	YES
Crop	YES	YES
Rotate	YES	YES
Zoom In/Out	YES	YES
Invert*	YES	YES
Sharpen	YES	YES
Measure*	YES	YES
Over/Under Exposure	YES	YES
Annotate*	YES	YES
Run on standard PC compatible computers	YES	YES
Supported Devices	Supported Device Families: • ScanX • ProVecta S-Pan • CamX	Supported Device Families: • ScanX • ProVecta S-Pan • CamX Same, plus this newly integrated device: SensorX

Descriptive Information	DBSWIN and VistaEasy Imaging Software K190629	DBSWIN and VistaEasy Imaging Software (Modified)
Computer 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 8.1, 64-bit Microsoft Windows 10, 64-bit Microsoft Windows Server 2012 Microsoft Windows Server 2016
CPU	≥ Intel Pentium IV compatible, 1.4 GHz	No change
RAM	≥ 1GB (2GB recommended)	No change
Drive	DVD-ROM	No change
Hard Disk	Workstation (without database) ≥50 GB The memory requirements of the database depend on the number of images taken at the office. (Camera image: Approx. 1 MB, X-ray image: Approx. 2 MB – 10 MB)	No change
Data Backup	Daily data back up	No change
Interface	Ethernet ≥ 100 Mbit	No change
Diagnostic Monitor	SVGA ≥ 17", ≥ 1024 x 768 pixel, 24/32 bit color depth	No change
Resolution /Graphics	≥ 1024 x 768 Depth of color 32-bit, 16.7 million colors	No change
Run on standard PC compatible computers	Yes	No change

*Not available on VistaEasy

9. <u>Discussion of Similarities and Differences:</u>

<u>Operating System:</u>

The list of compatible operating systems has changed. Windows 7 is no longer supported.

<u>Hardware compatibility:</u>

An additional hardware imaging source is supported by the DBSWIN software: the dental intraoral sensor "SensorX". SensorX is currently under review with the FDA (refer to the Traditional 510(k) K203116).

<u>Risk Analysis Update:</u>

In scope of the proof filter optimization for the dental camera CamX Spectra, newly identified risks have been identified and were added to the software risk analysis.

10. Non-Clinical Data and Performance Testing: Software was updated and validated in accordance with these standards and FDA guidance documents:

EN ISO 14971:2012 Risk Management FDA # 5-40

EN ISO 15223-1:2016 Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling And Information To Be Supplied FDA # 5-117

EN 62366-1:2015 + AC:2015 Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices FDA # 5-114

IEC 62304 Medical Device Software Life-cycle processes FDA # 13-79

FDA Guidance Documents employed:

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 and

Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005.

Documentation was generated for a Moderate Level of Concern.

Bench testing, effectiveness, and functionality were successfully conducted and verified with the compatible image capture devices. The software remains DICOM compliant.

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

12. 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 DBSWIN and VistaEasy Imaging Software is substantially equivalent to the predicate device as described herein. The minor device modifications to DBSWIN/VistaEasy 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 DBSWIN/VistaEasy can be found substantially equivalent to the predicate device as cleared in K190629.