



Food and Drug Administration
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Silver Spring, MD 20993-0002

Duerr Dental AG
%Ms. Suzanne Lucas
Quality Specialist/ Regulatory Affairs
Air Techniques, Inc.
1295 Walt Whitman Road
MELVILLE NY 11747

June 21, 2016

Re: K161444
Trade/Device Name: DBSWIN and VistaEasy Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 16, 2016
Received: May 25, 2016

Dear Ms. Lucas:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a faint, large watermark of the FDA logo.

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

Indications for Use

510(k) Number (if known)

K161444

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 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.

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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Special 510(k) SUMMARY

General Information

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Date Prepared: May 13, 2016

Device

Name of Device: DBSWIN and VistaEasy Imaging Software
Common or Usual Name: Radiological Image Processing System
Classification Name: Picture archiving and communications system (21 CFR 892.2050)
Regulatory Class: II
Primary Product Code: LLZ

Predicate Device

| Manufacturer | Product Name | 510(k) No. |
|---------------------|---------------------------------------|-------------------|
| Duerr Dental AG | DBSWIN and VistaEasy Imaging Software | K143290 |

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 defeatured version of DBSWIN.

Indication 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.

Predicate Similarities and Technological Comparison:

DBSWIN and VistaEasy are software devices that do not come in contact with patients, and do not control life sustaining devices. The technological differences between the subject device (DBSWIN/VistaEasy 5.10) and the predicate device (DBSWIN/VistaEasy 5.6) that are the subject of this Special 510(k) can be grouped into two main categories: 1) Support for additional devices; and 2) Software changes to improve functionality. The following table provides a comparison of the subject device and the predicate device.

Device Comparison Table

| Parameters | Predicate Device DBSWIN/VistaEasy v5.6 K143290 | Subject Device DBSWIN/VistaEasy v5.10 |
|--|--|--|
| Indications for Use | <p>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.</p> <p>DBSWIN and VistaEasy software are not intended for mammography use.</p> | Identical |
| Patient Management* | Yes | Yes |
| Image Management | Yes | Yes |
| Acquire Images | | |
| 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 |
| Save/Store Images* | Yes | Yes |

| Parameters | Predicate Device DBSWIN/VistaEasy v5.6 K143290 | Subject Device DBSWIN/VistaEasy v5.10 |
|--|---|--|
| 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 |
| Annotate* | Yes | Yes |
| Run on standard PC-compatible computers | Yes | Yes |
| Supported Devices | VistaCam iX Proof VistaCam iX Cam VistaCam iX Macro VistaPano S ProVecta S-Pan ScanX Swift | VistaCam iX Proof CamX Spectra VistaCam iX Cam CamX Elara CamX Polaris VistaCam iX HD CamX Triton HD CamX Luna HD VistaCam iX Macro VistaPano S ProVecta S-Pan VistaPano S CEPH ProVecta S-PAN CEPH ScanX Swift ScanX Duo ScanX Classic ScanX Ortho ScanX Intraoral |

*Denotes features that are unavailable on VistaEasy.

Clinical and Non-Clinical Testing include:

- DBSWIN/VistaEasy was developed in compliance with the harmonized standard of IEC 62304 for medical device software life cycle requirements.
- DBSWIN product has been in sales and distribution in the European dental market for over 15 years serving and performing the same intended use, functionality, and hardware compatibility interfaces with 3rd party software.
- Bench testing, effectiveness, and functionality were successfully conducted and verified between DBSWIN and VistaEasy, and image capture devices.
- DBSWIN is DICOM compliant.
- Risk Analysis based design development and design reviews were conducted.
- Full functional software cross check testing was performed.

Minimum System Requirement for Computer Imaging Systems and Differences between DBSWIN and VistaEasy:

| Hardware Requirements | DBSWIN/ VistaEasy |
|---|--|
| Platform | Microsoft Windows 7, 32 bit (from Home Premium), Microsoft Windows 7, 64 bit (from Home Premium), Microsoft Windows 8, 64 bit (not Windows RT), Microsoft Windows 10, 64-bit Microsoft Windows Server 2012 |
| CPU | ≥ Intel Pentium IV compatible, 1.4 GHz, ≥ Intel Core i3 |
| RAM | ≥ 1GB (2GB recommended), ≥ 4 GB |
| Drive | DVD-ROM |
| Hard Disk | Workstation (without database) ≥50 GB |
| Data Backup ¹ | Daily data back up |
| Interface | Ethernet ≥ 100 Mbit |
| Diagnostic Monitor | SVGA ≥ 17", ≥ 1024 x 768 pixel, 24/32 bit color depth |
| Resolution /Graphics | ≥ 1024 x 768 |
| Run on standard PC-compatible computers | Yes |

¹ Daily data backup is not required for VistaEasy since it does not allow the storage of data.

Conclusions

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 K143290.