



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Durr Dental Ag
% Ms. Suzanne Lucas
Air Techniques, Inc
1296 Walt Techniques, Inc
Melville, New York 11747

September 8, 2016

Re: K150672

Trade/Device Name: VistaCam iX “Proof”
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: April 24, 2015
Received: May 26, 2015

Dear Ms. Lucas:

This letter corrects our substantially equivalent letter of January 27, 2016

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" (21CFR 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,

A handwritten signature in black ink that reads "Susan Runno DDS, MA". The signature is written in a cursive style. A faint, large "FDA" watermark is visible in the background behind the signature.

Tina Kiang, Ph.D
Acting Division Director
Science and Policy
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K150672

Device Name
VistaCam iX "Proof"

Indications for Use (Describe)

The VistaCam iX "Proof" is intended to be used as an aid in the detection and diagnosis of dental caries.

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
VistaCam iX "Proof"

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

1. Date Summary Prepared:

January 21, 2016

2. Submitter's Identification:

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3. Device:

Trade /Proprietary Name:	VistaCam iX "Proof"
Common Name:	Intraoral Camera with Fluorescence Caries Detection Aid
Classification:	21 CFR 872.1745; Laser Fluorescence Caries Detection Aid
Product Code:	NBL

510(k) Summary
VistaCam iX “Proof”

4. Predicate Device:

Spectra Fluorescence Caries Detection Aid Device by Air Techniques, Inc.
510K# K090169

5. Device Description:

The VistaCam iX “Proof” aids in the detection and diagnosis of caries. It consists of a toothbrush-sized handpiece and a “Proof” head. A USB cable connects the handpiece to a personal computer with PACS software such as DBSWIN to enable communication between a PC computer and the handpiece.

After a camera cover is placed over the distal end, and an autoclave-able spacer is installed, the Handpiece is positioned over the tooth to be examined. The camera functions by illuminating the tooth surface with a light that causes the bacteria resident in carries to fluoresce. The fluoresced light is then converted into an electrical signal, sent to a computer, converted into an image (by imaging software) and presented on a monitor in multiple colors to illustrate suspected areas of decay.

6. Indications for use:

The VistaCam iX “Proof” is intended to be used as an aid in the detection and diagnosis of dental caries.

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

Dürr Dental’s VistaCam iX “Proof” is identical in terms of indications for use and the technology to the Spectra caries detection aid manufactured by Air Techniques’. Whose predicate dental devices are currently in commercial distribution and US-FDA cleared under 510K #K090169.

Table 1 below, summarizes the technological characteristics of VistaCam iX “Proof” vs. the predicate device.

510(k) Summary
VistaCam iX "Proof"

Table 1: Comparison to the Predicate device:

Comparison criteria	New device VistaCam iX "Proof" 510K # K150672	Predicate device Air Technique's Spectra Fluorescence Caries Detection Device 510K #K090169
Owner/ Operator	Dürr Dental AG	Dürr Dental AG
Manufacturer	Dürr Dental AG	Air Techniques, Inc
Similarities		
Intended use	Caries detection aid	Caries detection aid
Indications for use	The VistaCam iX "Proof" is intended to be used as an aid in the detection and diagnosis of dental caries.	The Spectra is indicated as an aid in the detection and diagnosis of dental caries.
Technology	Fluorescence technology to aid in the detection of carious lesions	Fluorescence technology to aid in the detection of carious lesions
Mode of operation	Excites bacteria to fluoresce	Excites bacteria to fluoresce
Image evaluation	Same as predicate	Image Color Relative level Green: 0 - 1.0 Blue: 1.0 - 1.5 Red 1.5 - 2.0 Orange 2.0 - 2.5 Yellow 2.5 - 3.0 Lighter colors and higher numbers indicate an increasing magnitude of the red / green fluorescence ratio and the likelihood of poorer tooth health.
Detection wavelength	495 nm	495 nm
Power Supply	Uses power from PC USB port	Uses power from PC USB port
Returned light	Fluorescence	Fluorescence
Differences:		
Enclosure	ASA+PC (Acrylonitrile Styrene Acrylate + Polycarbonate)	ABS (Acrylonitrile Butadiene Styrene) Plastic
Intensity	3 mW/cm squared at 8mm	3.5 mW/cm squared at 10mm
Light source	Utilizes 4 Violet LEDs with light collecting lens.	Utilizes 6 Violet LEDs with light collecting lens.
Lens	2 Dürr Dental lenses	4 Dürr Dental lenses

510(k) Summary
VistaCam iX "Proof"

Comparison criteria	New device VistaCam iX "Proof" 510K # K150672	Predicate device Air Technique's Spectra Fluorescence Caries Detection Device 510K #K090169
Software:	VistaCam iX "Proof" driver software and DBSWIN. VistaCam iX "Proof" can only be used with DBSWIN imaging software	ATI Spectra driver software and Visix.
Operating environment	10-40 C 20 to 75% RH non-condensing	10-40 C 10 to 90% RH non-condensing
Length	7.48 inches	8.6 inches
Width	1.03 inches	0.87 inches
Height	1.03 inches	1.15 inches
Spacers	8 mm	10 mm

8. Discussion of Differences:

- i. Enclosure: The material of composition for VistaCam iX "Proof" is substantially equivalent to that of Spectra enclosure as both these materials are non-carcinogenic and poses no health hazards as per their MSDSs. The enclosure of the VistaCam iX "Proof" was safety tested by Intertek to IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. The enclosure of the Spectra was safety tested by Underwriters Laboratory to IEC 60601-1:1988 +A1:1991 +A2:1995, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- ii. Intensity: The intensity for VistaCam iX is 3 mW/cm squared at 8mm and for Spectra is 3.5 mW/cm squared at 10mm. The difference in intensity of these devices does not impact VistaCam iX "Proof's" performance, safety and effectiveness. VistaCam iX's performance is demonstrated in the document - Executed validation report.
- iii. Light source and Lens: VistaCam iX "Proof" uses 4 violet LEDs and 2 lenses whereas Spectra use 6 violet LEDs and 4 lenses. The difference in the number of lenses and LED's has geometrical and constructional/ design reasons.

The function of lens is to focus the image of an object (surface of a tooth) onto the image sensor (CCD). As the "Proof" spacers are "shorter" (8mm), the camera and thus the image sensor is closer to the surface

510(k) Summary
VistaCam iX "Proof"

during image capturing. Therefore less lenses and LED's are needed for gaining a similar picture section and image quality. Most importantly, for both cameras, the recorded object area is nearly the same for the given distance, which is defined by the spacer. This difference in number of LEDs and lenses does not impact device's performance. VistaCam iX "Proof's" performance is demonstrated in the document - Executed validation report.

- iv. Software: VistaCam iX "Proof" works with VistaCam iX "Proof" driver software and Spectra device works with ATI Spectra driver software. Both VistaCam iX "Proof" and Spectra uses same algorithm developed for VistaCam iX by Duerr. VistaCam iX "Proof" can only be used with DBSWIN imaging software as opposed to Visix for Spectra. The compatibility of VistaCam iX "Proof" and DBSWIN is demonstrated by the DBSWIN software documents that are provided.
- v. Operating environment: The difference in the limits for relative humidity for VistaCam iX and Spectra is very minor and has no impact on the substantial equivalence of VistaCam iX.
- vi. Spacers: The 8 mm spacers for VistaCam iX "Proof" are exactly the same as the 10 mm spacers for Spectra in terms of shape and material* of construction. Moreover these are purchased from the same supplier. The 2 mm difference in the size of these spacers is not a significant change in their dimensions and thus has no impact on their performance and/or sterilization characteristics. The Sterilization validation study was performed on the 10 mm Spectra spacers in 2009 per ISO 11134:1994, Sterilization of health care products -- Requirements for validation and routine control -- Industrial moist heat sterilization, by Nelson laboratories. Nelson has provided their rationale dated October 27, 2015 to support the validity of the Sterilization validation for Spectra Spacers performed to ISO 11134:1994 in 2009 and it's conformance to the requirements of current FDA recognized standard, ISO 17665-1, Sterilization of health care products moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

**Septon plus a UV stabilizer (2-5-chloro-2H-benzotriazole-2-yl)-6-(1,1-dimethylethyl)- 4-methylphenol (CAS-No. 3896-11-5) with the restriction SML(T) =30 mg/kg.*

9. Non-Clinical Data

The purpose of the evaluation was to demonstrate substantial equivalence based on similar performance between the new device, the VistaCam iX “Proof” and the predicate device, Spectra Fluorescence Caries Detection Aid. Key performance attributes tested and compared include:

- a. LED Illumination and output
- b. Image Quality
- c. Color Separation

Validation and verification test results showed that new device and the predicate device are equivalent, and that illumination and fluorescence of potential caries detection products are similar for both Dürr Dental AG’s VistaCam iX “Proof” and Air Techniques’ Spectra camera.

10. Performance Testing

Dürr Dental AG’s VistaCam iX “Proof” complies with IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (3rd edition) - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, IEC 60601-1-2:2014 (4th edition) - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, and IEC 80601-2-60:2012 (first edition) Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment.

11. Biocompatibility Assessment

There is no biocompatibility issues known to be associated with any of the materials used to manufacture the VistaCam iX “Proof”. Patient contact Distance Spacer component was tested and complies with ISO 10993-10:2002 Standard and Amendment 1, “Biological Evaluation of Medical Devices, Part 10-Tests for Irritation and Delayed-Type Hypersensitivity”, and ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity.

By design, many of the components of the VistaCam iX “Proof” are isolated from patient contact by a camera cover or through a distance spacer. Components that have no patient contact are:

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VistaCam iX "Proof"

- Hand piece housing – ASA+PC (Acrylonitrile Styrene Acrylate + Polycarbonate)
- Lens window- Glass*
- Handpiece control buttons – Polyester
- Umbilical - Silicone

Components that contact the patient are:

- Camera cover*
Ethylene methyl acrylate copolymer and low density polyethylene
- 8 mm Spacer*
Septon plus a UV stabilizer (2-5-chloro-2H-benzotriazole-2-yl)-6-(1,1-dimethylethyl)- 4-methylphenol (CAS-No. 3896-11-5) with the restriction SML(T) =30 mg/kg

*These materials are currently in use and market distribution with the predicate device "Spectra Fluorescence Caries Detection Aid System" device, 510K# K090169.

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 AG concludes that the VistaCam iX "Proof" is substantially equivalent to the predicate device as described herein.

The differences between the new device and the predicate device shown in the comparison table above do not raise any new questions about safety and effectiveness and so we consider it substantially equivalent to the predicate device.