Duerr Dental AG
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

November 22, 2017

Re: K172007
Trade/Device Name: CamX Triton HD Proxi Head
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser fluorescence caries detection device
Regulatory Class: Class II
Product Code: NTK
Dated: October 5, 2017
Received: October 10, 2017

Dear 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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172007

Device Name
CamX Triton HD Proxi Head

Indications for Use *(Describe)*
The CamX Triton HD Proxi Head is a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary, DUERR DENTAL AG, CamX Triton HD Proxi Head K172007

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

1. Date Summary Prepared:

September 21, 2017

2. Submitter's Identification:

DUERR DENTAL AG
Höpfigheimer Strasse 17
74321 Bietigheim-Bissingen
Deutschland/Germany
Phone: + 49 (0) 7142 70 5-0
Fax: + 49 (0) 7142 705-500
E-Mail info@duerr.de Internet:
www.duerrdental.com

Contact:
Oliver Lange
Head of Quality Management
DUERR Dental AG Höpfigheimer
Strasse 17
D-74321 Bietigheim-Bissingen
Deutschland / Germany
Phone: + 49 (0) 7142 / 705-0
Fax: + 49 (0) 7142 / 705-500
Email: lange.o@duerr.de

U.S. Contact:
Suzanne Lucas
Air Techniques, Inc.
1295 Walt Whitman Road
Melville, NY 11747
Tel: 516-214-5514
Email: slucas@airtechniques.com

3. Device:

Trade /Proprietary Name:	CamX Triton HD Proxi Head
Device:	Caries Detector, Laser Light, Transmission
Regulation Description:	Laser fluorescence caries detection device.
Medical Specialty:	Dental
Product Code:	NTK
Regulation Number:	872.1745
Device Class:	2

4. Predicate Devices:

DIAGNOcam 2170 (K123402); Kaltenbach & Voigt GmbH,
DIFOTI USB2.0 System (K043068), ELECTRO-OPTICAL SCIENCES, INC.
Transillumination Cable Ti2200 K071429), Sybron Dental Specialties, Inc
For all of these predicates:

Device:	Caries Detector, Laser Light, Transmission
Regulation Description:	Laser fluorescence caries detection device.
Medical Specialty:	Dental
Product Code:	NTK
Regulation Number:	872.1745
Device Class:	2

5. Device Description:

The CamX Triton HD "Proxi" aids in the detection and diagnosis of proximal caries. It consists of a toothbrush-sized handpiece and a "Proxi" 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 (single patient disposable sheath, K132953) is placed over the distal end, and an autoclave-able spacer is installed, the Handpiece is positioned over the teeth to be examined. The camera functions by transilluminating sound tooth enamel with infrared light. Areas that spread and reflect the light (e.g. caries lesions) show up clearly delimited bright areas. A digital camera converts the object situation into an electrical signal, sent it over USB to a computer, converted into an image (by imaging software) and presented on a monitor in monochrome colors to illustrate suspected areas of decay.

6. Indications for use:

The CamX Triton HD Proxi Head is a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions.

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

Duerr Dental's CamX Triton HD Proxi Head is substantially equivalent in terms of indications for use and the technology to the predicate devices which are currently in commercial distribution.

Table 1 below, summarizes the technological characteristics of CamX Triton HD Proxi Head vs. the predicate devices.

Summary of the Technological Characteristics

Descriptive Information	CamX Triton HD Proxi Head (new product)	DIAGNOcam 2170 (K123402)	DIFOTI USB 2.0 System (K043068)	Transillumination Cable TI2200 (K071429)
Indication for Use	The CamX Triton HD Proxi Head is a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions	The DIAGNOcam 2170 is a diagnostic aid for the detection of open or incipient caries lesions above the gingiva and for monitoring the progress of such lesions. Indications: - Detection of smooth surface caries - Detection of occlusal caries - Detection of proximal caries - Detection of secondary caries - Detection of cracks	The DIFOTI USB 2.0 System (DIFOTI System for Dental Examinations, Model B) is indicated for detection of frank or incipient caries lesions above the gum line, and for monitoring the progression of such lesions.	The TI2200 Transillumination Cable is a diagnostic aid used to locate decay, calculus, fracture lines, endodontic orifices, cracks and fissures underneath the tooth surface utilizing a fiber optic cable and handle attached to a light source
Design	Handheld device	Identical	Identical	Identical
Functional Principle	Transillumination It makes use of the tooth structure which has the ability of light transmission. If the light transmission is interrupted due to caries lesions a bright area appears (inverse to e.g. DIAGNOcam 2170)	Transillumination It makes use of the tooth structure which has the ability of light transmission. If the light transmission is interrupted due to caries lesions a dark shadow appears.	Transillumination It makes use of the tooth structure which has the ability of light transmission. If the light transmission is interrupted due to caries lesions a dark shadow appears.	Transillumination It makes use of the tooth structure which has the ability of light transmission. If the light transmission is interrupted due to caries lesions a dark shadow appears.
Device Components	Handheld device with USB cable and software	Identical	Identical	Handheld device with cable and unit.

Descriptive Information	CamX Triton HD Proxi Head (new product)	DIAGNOcam 2170 (K123402)	DIFOTI USB 2.0 System (K043068)	Transillumination Cable TI2200 (K071429)
Light Source	Two LED are used to generate the exact wavelength being detectable by the CMOS sensor.	An internal laser diode is used to generate the exact wavelength being detectable by the CCD sensor.	An internal laser diode is used to generate the exact wavelength being detectable by the CCD sensor.	External light source
Installation	The computer based installation enables the customer to update the software	The computer based installation enables the customer to update the firm- and software	The computer based installation enables the customer to update the firm- and software	Independent (no software)
Power Source	USB-5V	Identical	Identical	N/A
Compatibility	USB connection	Identical	Identical	Specific connection
Compliance to Standards	IEC 60601-1	IEC60601-1, UL60601-1	IEC60601-1, UL60601-1	Not specified
Autoclaveable	Yes (distance spacer of the product)	Yes (tip of the product)	No (tip of the product is disposable)	No
Portable	No	Identical	Identical	Identical
Software	The software is a computer based software, which is controlling: - Show / display the pictures - Store / save the pictures - Live stream - Steering of camera function	The software consists of a product firmware and a computer based software, which is controlling: - Show / display the pictures - Store / save the pictures - Life stream - Steering of camera function	The software consists of a product firmware and a computer based software, which is controlling: - Show / display the pictures - Store / save the pictures - Life stream - Steering of camera function	No software
Intended Users	Dentist	Identical	Identical	Identical
Wavelength	850 nm	788 nm	670 nm	Not specified
Output power	2 sources (together ~4,5mW) max. 4,1 mW / cm² at a distance of 7 mm (spacer)	2 sources (each ~2mW) max. 21 mW / cm²	2 sources (left side ~1mW, right side ~3mW) max. 41 mW/cm²	Not specified

8. Discussion of Differences:

i. Functional Principle: The main function is based on transillumination, same as the predicate devices. The only difference is the image information of the CamX Triton HD Proxi is displayed inverted in comparison to the predicate devices.

ii. Light source : CamX Triton HD Proxi uses 2 infrared LEDs whereas other devices use a laser light source. The difference has geometrical and constructional/ design reasons. The predicate devices use light guides to bring the laser light to the tooth surface, in contrast to the CamX Triton HD Proxi has a direct illumination by LED in the distal end.

iii. Wavelength: The wavelength which is used (850 nm) is a little bit higher than the wavelength used by the predicate devices. The wavelength of the CamX Triton HD Proxi is optimized for the ability of light transmission of the sound enamel and for the sensitivity of the used CMOS image sensor.

iv. Output power: The output power for CamX Triton HD Proxi is 4,5 mW and for DIAGNOcam and DIFOTI the output power is about 4 mW (the two sources in addition, each).

9. Non-Clinical Data and Performance Testing

The purpose of the evaluation was to demonstrate substantial equivalence based on similar performance between the new device, the CamX Triton HD Proxi and latest predicate device, DIAGNOcam 2170. Key performance attributes tested and compared include:

a. LED Illumination and output
b. Image Quality

Validation and verification test results showed that new device and the predicate device are equivalent, and that illumination and image quality of potential caries detection products are similar for both Duerr Dental AG's CamX Triton HD Proxi and KaVo's DIAGNOcam camera. Duerr Dental AG's CamX Triton HD Proxi complies with IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (edition 3) - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, IEC 60601-1-2:2014 (edition 4) - 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. Sterilization validation testing was successfully performed according to ANSI/AAMI/ISO 17665-1, Annex D and the validation approach outlined in ANSI/AAMI/ISO 14937, Annex D (Approach 3).

10. Biocompatibility Assessment

There are no biocompatibility issues known to be associated with any of the materials used to manufacture the CamX Triton HD Proxi. 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 CamX Triton HD Proxi are isolated from patient contact by a camera cover and through a distance spacer. Components that have no patient contact are:

- Hand piece housing
- Lens window-
- Handpiece control buttons –
- Umbilical -

Components that contact the patient are:

- Camera cover*
- 8 mm Spacer*

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

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, Duerr Dental AG concludes that the CamX Triton HD Proxi 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.