November 23, 2019

Kaltenbach & Voigt GmbH
℅ Frank Ray
Regulatory Affairs Manager
KaVo Dental Technologies, LLC
11727 Fruehauf Drive
Charlotte, North Carolina 28273

Re: K182712
Trade/Device Name: DEXIS CariVu 3-in-1 by KaVo
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NTK, NBL
Dated: October 18, 2019
Received: October 21, 2019

Dear Frank Ray:

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,

Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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)*
K182712

Device Name
DEXIS CariVu 3-in-1 by KaVo

Indications for Use *(Describe)*
The DEXIS CariVu 3-in-1 by KaVo acquires patient images as a diagnostic aid for detection of smooth surface caries, occlusal caries, proximal caries, initial caries, secondary caries, and tooth cracks. The DEXIS Cari Vu 3-in-1 by KaVo is designed for use by a trained professional in the field of dentistry.

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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K182712 – 510(k) Summary

for

DEXIS CariVu 3-in-1 by KaVo

1. Submitter Information**:**

Kaltenbach & Voigt GmbH
Bismarckring 39
88400 Biberach
Germany

Contact Person: Frank Ray
Telephone Number: (704) 587-7227
Fax Number: (704) 587-7250

Date Prepared: November 22, 2019

2. Device Name:

- Proprietary Name: DEXIS CariVu 3-in-1 by KaVo
- Manufacturer: Kaltenbach & Voigt GmbH
- Common Name: Laser fluorescence caries detection device
- Classification Name: Caries Detector, Laser Light, Transmission
- CFR Number: 872.1745
- Device Class: II
- Product Code: NTK, NBL

3. Primary Predicate Device:

- Proprietary Name: DIAGNOcam 2170 (K123402)
- Manufacturer: Kaltenbach & Voigt GmbH
- Common Name: Laser fluorescence caries detection device
- Classification Name: Caries Detector, Laser Light, Transmission
- CFR Number: 872.1745
- Device Class: II
- Product Code: NTK

Reference Device 1:

- Proprietary Name: CamX Triton HD Proxi Head (K172007)
- Manufacturer: Duerr Dental AG
- Common Name: Laser fluorescence caries detection device
- Classification Name: Caries Detector, Laser Light, Transmission
- CFR Number: 872.1745
- Device Class: II
- Product Code: NTK

Reference Device 2:

- Proprietary Name: VistaCam iX "Proof" (K150672)
- Manufacturer: Duerr Dental AG
- Common Name: Laser fluorescence caries detection device
- Classification Name: Caries Detector, Laser Light, Transmission
- CFR Number: 872.1745
- Device Class: II
- Product Code: NBL

4. Description of Device:

The camera enables various applications in health facilities/dental offices, dental clinics, orthodontics and oral and maxillary surgery. Connected to a computer, a monitor and imaging software such as CONEXIO, the DEXIS CariVu 3-in-1 by KaVo can be used to create and save images and videos.

The device is used as an intraoral camera to acquire images in the oral cavity of the patient. The camera combines three different known applications from available intraoral cameras in one device. These applications are standard camera functionality, transillumination and fluorescence caries detection. Therefore, the camera uses different light colors for each of the three applications to illuminate the tooth. In combination with an optical system, CMOS sensor, and an internal image processing unit, a digital image of the tooth is generated. The live images are transferred as a standard mjpg video stream via USB interface to a running computer and can interface with a dental imaging software such as for example CONEXIO for basic intraoral camera management functionality.

The device may be used as an aid for monitoring caries lesion size and shape by comparing images taken with the Dexis CariVu 3-in-1 by KaVo over time, by using different reference points, such as tooth contour and position, to position the device to optimize capturing tooth features previously recorded in a still or video image.

For easy use the camera is equipped with an autofocus mechanism which will provide a sharp representation of the tooth which is placed in the center of the image. The autofocus provides the ability to have sharp images from close distances of about 2mm to about 120mm distance.

The different operation modes are described as follows:

1.) Color mode:
For normal color images, a white LED for illumination is used. With this light the camera provides coloured images or videos. The camera can be used with or without a Tip Vision Full HD which is required for illumination for the transillumination mode.

2. Fluorescence mode:
For the fluorescence mode the blue LED illumination is used. The blue light excites bacterial porphorines as an aid to detect caries.

To enhance the image quality and to minimize external light influence on the fluorescence effect the accessories Fluorescence Cover Vision Full HD can be used optionally with the camera. The Fluorescence Cover Vision Full HD is a rubber cap which can be slipped on the front camera head and prevent or minimize external light on the images surface of the tooth. After each usage the Fluorescence Cover Vision Full HD will be reprocessed separately.

The camera can be used with or without a Tip Vision Full HD which is required for illumination for the transillumination mode. This mode is used to record images and videos to aid in the diagnosis of caries (mainly in the occlusal area) and plaque by means of fluorescent effect.

3. Transillumination mode (by the use of near infrared light):
The transillumination mode provides images to aid in the detection of caries. For this mode near infrared light will be used. The near infrared light penetrates the side of the tooth near gingiva and illuminates the enamel of the tooth to produce gray scale images whereby intact enamel appears bright, and defects such as caries or cracks result in diffusion of light path and create an area of dark appearance.

To use this mode, the Tip Vision Full HD must be attached to the device as the LEDs for the illumination are located inside the Tip Vision Full HD. The Tip Vision Full HD touches the side of the tooth and gingiva and illuminates it from two sides whereas the image is taken from the top.

The DEXIS CariVu 3-in-1 by KaVo is available in two similar models. The differences between the models are a wall mounted version to store the device with a cable length of 2.5 meters (model 1.011.4444) and a table holder version to store the device on a dental unit with a cable length of 1.55 meters (model 1.013.1700). All critical components within the DEXIS CariVu 3-in-1 by KaVo are common. A disposable sheath is used with the device to mitigate the potential for cross contamination.

5. Indications for Use:

The DEXIS CariVu 3-in-1 by KaVo acquires patient images as a diagnostic aid for detection of smooth surface caries, occlusal caries, proximal caries, initial caries, secondary caries, and tooth cracks. The DEXIS Cari Vu 3-in-1 by KaVo is designed for use by a trained professional in the field of dentistry.

6. Comparison to Predicate Device:

The proposed device (DEXIS CariVu 3-in-1 by KaVo) from Kaltenbach & Voigt GmbH function in a manner similar to and are intended for the same indications for use as the primary predicate device DIAGNOcam 2170 (K123402) marketed by Kaltenbach & Voigt GmbH. There are numerous identical design and technological characteristics such as Transillumination, CMOS sensor high performance, Power Source (USB - 5V), orientation of light source transillumination mode, and Optical System. Also, both the proposed device and the predicate device have an identical Principles of Operation (Transillumination) as they use the tooth structure which has ability of light transmission. If the light transmission is interrupted due to caries lesions a dark shadow appears.

Furthermore, the proposed device has an identical Principle of Operation (Fluorescence Mode) as the Reference Device #1 CamX Triton HD Proxi Head (K172007) and Reference Device #2 VistaCam iX "Proof". The Technical Specifications Optical Radiation I/O Mode, Orientation of Light Source I/O Mode, and the Optical Radiation Fluorescence Mode are identical.

However, there are different technological characteristics such as the proposed device has a Resolution of 1920 x 1080px where the Primary Predicate device has 640 x 480px and the image size (9,2mm working distance) is 27 x 14 mm for the proposed device and is 20 x 13 mm for the Primary Predicate device. The proposed device is 253mm long compared to the primary predicate device being 245mm long.

These different technological characteristics do not raise new concerns of substantial equivalence. The device comparison table below for the DEXIS CariVu 3-in-1 by KaVo (proposed device) and the DIAGNOcam 2170 (primary predicate device) are substantially equivalent in terms of indication for use, technology and performance specifications as the few differences between the proposed device and the predicate device do not impact substantial equivalence. The performance testing results provided in this submission supports that the proposed device performs as well as the primary predicate and reference device for its intended use.

Device Comparison Table:

Descriptive Information	**Proposed Device** **DEXIS CariVu 3-in-1 by KaVo**	**Primary Predicate Device** **DIAGNOcam 2170 (K123402)**	**Reference Device #1** **CamX Triton HD Proxi Head (K172007)**	**Reference Device #2** **VistaCam iX "Proof" (K150672)**
Indications for Use				
Indications for Use	The DEXIS CariVu 3-in-1 by KaVo acquires patient images as a diagnostic aid for detection of smooth surface caries, occlusal caries, proximal caries, initial caries, secondary caries, and tooth cracks. The DEXIS Cari Vu 3-in-1 by KaVo is designed for use by a trained professional in the field of dentistry.	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 carries *Detection of proximal caries *Detection of initial caries *Detection of secondary caries *Detection of cracks The device is intended for use in a dentist's office or dental clinic.	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. See **Note*** above	The VistaCam iX "Proof" is intended to be used as an aid in the detection and diagnosis of dental caries.
Device Design				
Design	Handheld device	Handheld device	Handheld device	Handheld device
Operational Modes	Color Fluorescence Transillumination	Transillumination	Color Fluorescence Transillumination	Fluorescence
Installation	Computer based software which enables the user to update the software	Computer based software which enables the user to update the software	Computer based software which enables the user to update the software	Computer based software which enables the user to update the software
Dimension (Handpiece length)	253mm	245 mm	200mm	190mm
Power Source	USB - 5V	USB - 5V	USB - 5V	USB - 5V

Compatibility	USB 2 or USB 3 connection	USB 2 or USB 3 connection	USB 2 or USB 3 connection	USB 2 or USB 3 connection
Autoclavable	Yes (Tip and fluorescence cover of the product)	Yes (Tip of the product)	Yes (Distance spacer (fluorescence cover) of the product)	Yes (Distance spacer (fluorescence cover) of the product)
LED's/Wavelength	Color: 2x white Fluorescence: 2 x UV (405nm) Transillumination: 2x nIR (850nm)	Transillumination: 2x laser diode(780nm)	Color: 2x white Fluorescence: 2 x UV (405nm) Transillumination: 2x nIR (850nm)	Color: 2x white Fluorescence: 4 x UV (405nm) Transillumination: 2x nIR (850nm)
Device adaptation when operation mode is changed	None, all components are integrated in the device	N/A	Change of heads required	Change of heads required
Optical System	Multiple lens system with protective glass	Multiple lens system with protective glass	Multiple lens system with protective glass	Multiple lens system with protective glass
Sensor	CMOS high performance	CMOS high performance	CMOS high performance	CCD Color Interline Transfer
Resolution	1920 x 1080px	640 x 480px	1280 x 1024px	704 x 576 px
Image size (9,2mm working distance)	27 x 14 mm	20 x 13 mm	13 x 8 mm	
Autofocus	Autofocus using liquid lens technology	Fix focus for a single working distance	Autofocus using liquid lens technology	Fix focus for a single working distance
Software	Computer based Software to Show/display pictures Show live stream Save pictures Steering of camera functions	Computer based Software to Show/display pictures Show live stream Save pictures Steering of camera functions	Computer based Software to Show/display pictures Show live stream Save pictures Steering of camera functions	Computer based Software to Show/display pictures Show live stream Save pictures Steering of camera functions

Non-Clinical Test Data:

Performance bench testing for the Dexis CariVu 3-in-1 by Kavo was performed according to international standards for Laser fluorescence caries detection devices. Also, testing for the Dexis CariVu 3-in-1 by Kavo was conducted to standards IEC 60601-1-2 Forth Edition (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance), ANSI AAMI ES60601-1 and IEC 60601-1:2005 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance), CAN/CSA-C22.2 No. 60601-1 (Medical Electrical Equipment - Part 1: General Req. for Basic Safety & Essential Performance), IEC 62304: 2006 Edition 1.1 (Medical device software - Software life cycle processes),ISO 17665-1 First edition (Sterilization of health care products - Moist heat), AAMI / ANSI ST79 2017 (Comprehensive guide to steam sterilization and sterility assurance in health care facilities),ISO 10993-1 Fourth Edition (Biological evaluation of medical devices), and ISO 7405 Second edition (Dentistry - Evaluation of biocompatibility of medical devices used in dentistry).

Moreover, ISO 14971 2007 and 2012 (Medical devices - Application of risk management to medical devices), Guidance for Industry and FDA Staff 2014-10-02 Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, and Guidance for Industry and FDA Staff 2017-06-09 Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling was performed.

Clinical Performance Data:
Clinical testing was not conducted on this product.

Conclusion as to Substantial Equivalence:
Based upon a comparison of indications for use and technological characteristics, together with results from non-clinical performance testing, we believe that DEXIS CariVu 3-in-1 by KaVo is substantially equivalent to the predicate devices.