K123402/5003

KaVo. Dental Excellence.

# Section V - 510(k) Summary

Submitter:

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SEP 2 4 2013

Date Summary Prepared: September, 24th 2013

Device Name:

- Trade Name - ***DIAGNOcam 2170***
- Common Name - Caries detector, laser light, transmission
- Classification Name - Laser fluorescence caries detection device, per 21 CFR § 872.1745

Devices for Which Substantial Equivalence is Claimed:

- DIFOTI USB 2.0 SYSTEM (K043068)
- Transillumination Cable Ti2200 (K071429)

Device Description:

The *DIAGNOcam 2170* is a handheld laser fluorescence caries detection device which uses the DIFOTI technology (Digital Imaging Fiberoptic Transillumination) as the functional principle. KaVo *DIAGNOcam 2170* delivers images, which are reminiscent of X-rays but which are completely radiation free – by means of a light that is especially adapted to this examination method. The tooth structures allow the passage of light from the entry site to the camera. Areas that block light transmission (e.g. carious lesions) show up clearly as well delimited, dark areas. A digital camera captures the actual situation and makes it visible in real-time on the screen. The USB connector provides electric power to the unit. The *DIAGNOcam 2170* will be delivered with a firmware (unit) at the handheld device which is responsible for steering of the camera functions and a computer based software (image) which is responsible to show / display the pictures, store / save the pictures and the possibility of a life stream. The internal laser diode generates an exact wavelength being detectable by the CCD sensor. The DIAGNOcam 2170 follows the international standards for electrical safety and electromagnetic compatibility which are applicable for the use with human beings. The *DIAGNOcam 2170* works with a laser wavelength at 788 nm and an output power of 2mW for each laser diode (2 sources). The maximum output power is 21mW/cm$^2$.

The life stream describes a way how the dentist can use the DIAGNOcam 2170. So it is possible to use the DIAGNOcam 2170 to see life images of the teeth and not only to have the possibility to make single pictures. While using the DIAGNOcam 2170 at the teeth the dentist can see real pictures / a video on his monitor.

The tips of the *DIAGNOcam 2170* can be sterilized according to the instructions for use. Two tips (small & large) are supplied with the handheld device. Additionally the *DIAGNOcam 2170* will be supplied with a holder for the device. This holder allows the dentist to deposit the *DIAGNOcam 2170* in a safe position. The holder is intended to be used outside the treatment for general storage.

Intended Use of the Device:

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.

Substantial Equivalence:

The *DIAGNOcam 2170* handheld laser fluorescence caries detection device is substantially equivalent to other legally marketed devices in the United States. The *DIAGNOcam 2170* functions in a manner similar to and is intended for the same use as the DIFOTI USB 2.0 SYSTEM marketed by Electro-Optical Sciences, inc. and to the Transillumination Cable Ti2200 marketed by Kerr Corporation. The *DIAGNOcam 2170* is similar to all three predicate devices in that it is a handheld laser fluorescence caries detection device which uses the transillumination as the functional principle. As the DIFOTI USB 2.0 SYSTEM an internal light source (laser diode) is used to generate the exact wavelength being detectable by the CCD sensor, a USB connection supplies the *DIAGNOcam 2170* with power and additional to that the DIFOTI USB 2.0 SYSTEM works with software consisting of a product firmware and a computer based software, which is responsible to show / display the pictures, to store / save the pictures, for the possibility of a life stream and for steering of the camera function.

The life stream describes a way how the dentist can use the DIAGNOcam 2170. So it is possible to use the DIAGNOcam 2170 to see life images of the teeth and not only to have the possibility to make single pictures. While using the DIAGNOcam 2170 at the teeth the dentist can see real pictures / a video on his monitor.

The *DIAGNOcam 2170* differs from the Transillumination Cable Ti2200 in that the *DIAGNOcam 2170* uses an internal light source and a USB connection. Furthermore does the Transillumination Cable Ti2200 not have software and it is not a handheld device by itself. The *DIAGNOcam 2170* differs from both predicate devices in that the *DIAGNOcam 2170* has autoclaveable tips (small & large).

## Summary of the Technological Characteristics:

| Descriptive Information | DIAGNOcam 2170 | DIFOTI USB 2.0 SYSTEM (K043068) | Transillumination Cable TI2200 (K071429) |
|---|---|---|---|
| Indications for Use | 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.<br>Indications:<br>• Detection of smooth surface caries<br>• Detection of occlusal carries<br>• Detection of proximal caries<br>• Detection of initial caries<br>• Detection of secondary caries<br>• 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 |
| Functional Principle | Transillumination<br>(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. | Identical | Identical |
| Device Components | Handheld device with USB cable and software | Identical | Handheld device with cable and unit |
| Light Source | An internal laser diode is used to generate the exact wavelength being detectable by the CCD sensor. | Identical | External light source |
| Installation | The computer based installation enables the customer to update the firm and software. | Identical | Independent (no software) |
| Power Source | USB - 5V | Identical | N/A |
| Compatibility | USB connection | Identical | Specific connection |
| Compliance to Standards | IEC 60601-1, UL 60601-1 | Identical | Not specified |
| Autoclaveable | Yes (tip of the product) | No (tip of the product is disposable) | No |
| Portable | No | Identical | Identical |
| Software | The software consists of a product firmware and a computer based software, which is controlling:<br>- Show / display the pictures<br>- Store / save the pictures<br>- Life stream<br>- Steering of camera function | Identical | No software |
| Intended Users | Dentists | identical | identical |
| Laser wavelength | 788 nm | 670 nm | Not specified |

| | | | |
|---|---|---|---|
| Output power | 2 sources (each ~2mW)<br>max. 21 mW / $cm^2$ | 2 sources (left side ~1mW, right side ~3mW)<br>max. 41 mW / $cm^2$ | Not specified |

Non-Clinical Test Data:

Temperature and energy tests according to the international standards for electrical safety and electromagnetic compatibility have been conducted to determine the conformance to the state of the art. Biocompatibility studies have been completed which demonstrate that the *DIAGNOcam 2170* is safe for his intended use.

Additionally, the *DIAGNOcam 2170* software has been successfully validated to confirm the performance of the device.

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the tests according to the international standards for electrical safety and electromagnetic compatibility, the biocompatibility studies, the similar technological / performance characteristics as compared to the predicate devices, and successful validation of the *DIAGNOcam 2170* software, the performance of the *DIAGNOcam 2170* is deemed to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 24, 2013

Kaltenbach & Voigt GmbH
Mr. Stefan Trampler
Head of Quality Management & Regulatory Affairs
Bismarchring 39
Biberach / Riss
Germany 88400

Re: K123402
Trade/Device Name: DIAGNOcam 2170
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NTK
Dated: September 2, 2013
Received: September 6, 2013

Dear Mr. Trampler:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Richard C. Chapman for

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Section IV - Indications for Use

510(k) Number (if known): K123402

Device Name: ***DIAGNOcam 2170***

Indications for Use:

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- Detection of cracks

Andrew I. Steen -S
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**(Division Sign-Off)**
**Division of Anesthesiology, General Hospital Infection Control, Dental Devices**

**510(k) Number:** K123402

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND / OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)