July 2, 2020

Good Doctors Co.,Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt,
Ste 200
Irvine, California 92620

Re: K183471
Trade/Device Name: IC-WHCD100 (Inspire)
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NBL
Dated: June 8, 2020
Received: June 9, 2020

Dear Priscilla Chung:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K183471

Device Name

IC-WHCD100 (Inspire)

Indications for Use *(Describe)*

The IC-WHCD100 (Inspire) 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.

510(k) Summary

(K183471)

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

Date: July 2, 2020

1. 510K Applicant / Submitter:

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2. Submission Contact Person

LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200, Irvine CA 92620
Priscilla Juhee Chung
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Proprietary Name: IC-WHCD100 (Inspire)
- Common Name: Intraoral camera with Caries Detection Aid
- Classification: Class II (21 CFR 872.1745)
- Product Code: NBL

4. Predicate Devices

- Primary Predicate: VistaCam iX Proof (K150672)

- Reference Device: CamX Triton HD Proxi Head (K172007), XRAY VISION (K983111), Planmeca Romexis (K171385), SIDEXIS 4 (K132773), DBSWIN And VistaEasy Imaging Software (K143290)

5. Description:

The IC-WHCD100 is a toothbrush-sized handpiece used for diagnosis of caries. A USB cable is used to connect the handpiece to a personal computer with a dental imaging software.

After a camera cover is placed over the end, the handpiece is positioned over the tooth to be examined. The camera takes images by illuminating the tooth surface with a white LED light for regular tooth image. With fluoresced light, the device can show bacteria on the surface of tooth. With infrared light, the device can show tooth cavity by highlighting enamel.
The user can view the images on 510k cleared dental imaging software such as Apteryx vision (k983111), Romexis (K171385), Sidexis (K132773), etc.

8. Indications for Use

The IC-WHCD100 (Inspire) is intended to be used as an aid in the detection and diagnosis of dental caries.

9. Substantial Equivalence Discussion:

The subject device has the same indications for use as the predicate devices. The power supply and lighting source are also the same.
The predicate device, VistaCam IX Proof, shows fluorescence image using 405nm light source and the reference device, CamX Triton HD Proxi Head, shows transillumination image using 840nm (infrared) light source. The subject device, IC-WHCD100, uses 405nm and 940nm (infrared), and offers both modes(fluorescence & transillumination) that VistaCam IX Proof and CamX Triton HD Proxi Head each offers.
The subject device uses 940nm, whereas, the reference device uses 840nm, however, the performance test results of the subject device supports that the transillumination mode works well despite this difference. The lens type and the resolutions are also different but again the performance test result supports that the subject device is substantially equivalent to the predicate devices.

	Applicant device	**Primary Predicate device**	**Reference Device**
Company	Good Doctors Co., Ltd.	Durr Dental AG	Durr Dental AG
Product name	IC-WHCD100(inspire)	VistaCam IX Proof	CamX Triton HD Proxi Head
Common name	Intraoral camera	Intraoral camera	Intraoral camera
Classification Regulation	21 CFR 872.1745 Laser Fluorescence Caries Detection Device	21 CFR 872.1745 Laser Fluorescence Caries Detection Device	21 CFR 872.1745 Laser Fluorescence Caries Detection Device
Classification name on FDA	Laser, Fluorescence Caries Detection	Laser, Fluorescence Caries Detection	Laser, Fluorescence Caries Detection
510(k) Number	K183471	K150672	K172007
Similarities			
Indication for	This device is an intraoral camera	The VistaCam iX	The CamX Triton HD

use	used to take images of the inside of the mouth or oral cavity.	"Proof" is intended to be used as an aid in the detection and diagnosis of dental caries.	Proxi Head is a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions
Technology	Transillumination and fluorescence technology to aid in the detection of carious lesions	Fluorescence technology to aid in the detection of carious lesions	Transillumination to aid in the detection of carious lesions
Detection wave length	940nm, 405nm	405 nm	840 nm
Power supply	USB 5V	USB 5V	USB 5V
Lighting source	LED	LED	LED
Sensor type	CMOS / 5M	CMOS	CMOS
Resolution	1280 x 720	1280 x 1024	1280 x 1024
Cable length	Approximately 3 meters	2.5 meters	2.5 meters
Operating environment	10-40 C 20 to 80% RH non-condensing	10-40 C 20 to 75% RH non-condensing	10-40 C 20 to 75% RH non-condensing
Appearance			
Differences			
Software	Can be use with other imaging software.	VistaCam iX "Proof" driver software and DBSWIN. VistaCam iX "Proof" can only be used with DBSWIN imaging software	-
Hand piece	Metal (Zinc + plating + UV	ASA+PC (Acrylonitrile	ASA+PC (Acrylonitrile

housing	coating)	Styrene Acrylate + Polycarbonate)	Styrene Acrylate + Polycarbonate)
Spacers	8 mm	8 mm	8 mm
Intensity	3mW/cm squared at 8mm	3 mW/cm squared at 8mm	4.1 mW / cm² at a distance of 7 mm
Lens	Liquid lens	2 Duerr Dental lenses	2 Duerr Dental lenses
Size / weight	129 x 21.5 x 32mm/ 61g (without cable)	7.48 x 1.03 x 1.03 inches / 50g (without cable)	7.48 x 1.03 x 1.03 inches / 50g (without cable)

10. Performance Tests (Non-clinical)

- Performance Test for imaging (Image Sharpness, Image Size, Image Resolution, tooth Caries Detection)
- EMC and Electrical Safety Testing in accordance with IEC 60601-1 & IEC 60601-1-2
- Software Validation Test
- Biocompatibility Tests (Cytotoxicity, Irritation, and Skin Sensitization) in accordance with ISO 10993-5 and ISO 10993-10.
- Cleaning and Disinfecting Validation Test by referencing ISO 10993-17, AAMI TIR12, AAMI TIR30, ASTM E2314-03, ISO 15883-1, ISO 15883-5, ISO 10993-12, ISO/TS 17665-2
- Optical Radiotin Safety Test in accordance with IEC 62471

The test results of non-clinical tests performed on the subject device supported that it is substantially equivalent to the predicate devices despite the differences.

11. Conclusions:

Based on the information provided in this premarket notification, Good Doctors Co., Ltd. concludes that the IC-WHCD100 (Inspire) is substantially equivalent to the predicate device as described herein in.