July 18, 2019

AIOBIO Co., Ltd.
% Kyoungju Kim
Official Correspondent
MDLab
Room 804, Botanic Park Tower Bldg., 161-17, Magokjungang-ro,
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KOREA

Re: K183121
Trade/Device Name: Qraypen
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: Class I
Product Code: EIA
Dated: April 17, 2019
Received: April 19, 2019

Dear Kyoungju Kim:

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 Assistant 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)*

K183121

Device Name

Qraypen

Indications for Use *(Describe)*

Qraypen is to be used as an intraoral video source and is indicated for individuals who may benefit from the addition of video images in intraoral dental examinations.

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.

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"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 - K183121

AIOBIO Co., Ltd. Qraypen, Dental Intraoral Camera

1. Submitter

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Date prepared: July 15, 2019

2. Device

Device Common/Usual Name: Dental Intraoral Camera
Device Proprietary Name: Qraypen
Device Classification: Class I

21 C.F.R. Section	Classification Name	Product Code
872.6640	Dental operative unit and accessories	EIA

3. Substantially Equivalent Device

Device Name	510(k) Number
CDR-CAM (SCHICK TECHNOLOGIES, INC)	K963778

4. Device Description

Qraypen, a Dental Intraoral Camera, provides digital color images of intraoral anatomy during oral health examinations by dentists or dental sub-specialists. The output of the images can be shown through a computer monitor. This product is designed only for the use in dentistry and may only be used by trained medical personnel. The Qraypen is not made as a caries detection device. Therefore, Qraypen is not claimed as a caries detection device.

(1) Main components of Qraypen

Qraypen is a hand-held device that consists of Qraypen Handpiece, Cradle, Cradle screw, USB 2.0 Cable, Adapter, and User manual. The Qraypen is connected to a compatible Windows PC and power supply by USB 2.0 type cable.

(2) Design features

a) An intraoral camera that is capable of both blue and white LED color imaging
b) Integral LED that allows the color of light to be changed
c) Automatic focusing
d) Compatible with any viewer program that meets the standards of USB video device class (UVC) 1.0 or higher

(3) Three modes are available:

a) White light mode: Qraypen captures images with white LED color light
b) Blue light mode: Qraypen captures images with blue LED color light
c) Orange light mode: Qraypen captures images with white and Blue LED color light in succession

(4) Technical Specifications

The summary of technical specifications was shown in the following table.

	Item		Detail
Product Specifications	Image sensor		HD720p C image sensor MOS Video image sensor
	Output resolution		MJPG 1280 x 720: 30fps (Default)
	Image transfer rate		YUY2 1280 x 720: 9fps
	LED	WHITE	7ea White chip LED
		UV	2ea UV chip LED
	Capture System		Hand-piece button capture
	Camera Connector		One touch full-metal connector
	Interface		PC USB 2.0
	Battery		AC/DC Adapter: 400mA, 100–240Vac, 50–60Hz Main Unit: 0.5A, 5Vdc
	Essential Performance		Auto focus (Image acquisition by taking oral cavity)
	Dimension		27 mm (Ø) x 227 mm (H)

	Weight	67 g

5. Indications for Use

Qraypen is to be used as an intraoral video source and is indicated for individuals who may benefit from the addition of video images in intraoral dental examinations.

6. Comparison of Technological Characteristics with the Predicate Device

The Qraypen and CDR-CAM, its predicate device, are dental intraoral cameras that employ the same basic scientific technology for the acquisition and the display of video images. Both are operated in the same manner in that lens and LED lights mounted on the head of the camera can be used to illuminate the oral cavity and check the state of the patient's oral health.

The Indications for use statement for Qraypen are similar to the predicate device. Both devices are intended for the visualization of oral cavity. They are intended to be used in clinical environments, including hospitals, clinics, and medical office settings, for the examinations of patients.

They are also hand-held devices and have compact designed handpieces connected directly to a desktop PC or laptop via a cable. Also, they have focusing functions and capture buttons to assist dentists for taking intraoral images of the patients.

Characteristic	**AIOBIO Co., Ltd.** **Qraypen**	**Predicate Device** **SCHICK TECHNOLOGIES, INC. CDR-CAM K963778**
Indications for Use	Qraypen is to be used as an intraoral video source and is indicated for individuals who may benefit from the addition of video images in intraoral dental examinations.	Schick Technologies Inc., CDR-cam Camera System is intended for use by practitioners in the dental field. The camera system is used to capture, view, and store intra- as well as extra-oral images. The images are used as an aid or adjunct in the diagnosis of anatomy as well as the communication of diagnosis to other dental professionals and / or patients. The camera handpiece is intended to be used with sterile sheaths so as to prevent the spread of infectious disease.
Target Population	For use in all patients	Identical
Anatomical sites	Oral cavity	Identical
Environment of Use	Hospital, clinic, and medical office settings	Identical
Intended Users	Dentists and sub-specialists	Identical
Power supply	AC/DC adaptor	Power supplied via USB
Design	Handheld device	Identical
Focus range	5 - 45 mm (0.2 -1.77 in)	5 - 45 mm (0.2 -1.77 in)

510(k) Summary - K183121

AIOBIO Co., Ltd. Qraypen, Dental Intraoral Camera

Characteristic	AIOBIO Co., Ltd. Qraypen	Predicate Device SCHICK TECHNOLOGIES, INC. CDR-CAM K963778
Focus type	Trigger AF (Autofocus)	Fixed
Imager	CMOS	CCD
Principle/Method of Operation	The lens and LED lights mounted on the head of the camera can be used to illuminate the oral cavity and to check the state of the patient's oral health. This Dental Intraoral Camera contains its own lighting function and is used in connection to a desktop PC or laptop computer in dentistry. It captures images of oral cavity and the images are shown on the computer monitor. It aids the assessment of oral health and can provide information for patient education.	CDR-CAM supports streaming video and still frame capture to help dental professionals demonstrate the current condition and post-treatment outcomes of their patients' dental health. Video frames can be archived with dental exams as permanent records and retrieved for comparison or subsequent review. CDR-CAM provides slim, smooth contours and a small head profile for comfortable use and operation. Taking images with the CDR-CAM integrated capture button makes video frame capture a simple one-pushbutton step. Bright, built-in LEDs supply superior illumination and advanced optics provide excellent depth of field for optimal performance.
Image Display	Desktop PC and laptop	PC workstation
Light source	Multiple LED	Identical
Camera Connection to Display	Wired (USB)	Identical
Software	Qraypen software	CDR DICOM software
System Components	Handheld device with USB cable and software	Identical
Disinfection	Disposable, single use plastic sleeve. The handpiece and cradle also be disinfected with 70% isopropyl alcohol solution.	Disposable, single use plastic sleeve. The handpiece and cradle also be disinfected with Cavi-Wipes (Metrex Research, Kerr)
Portable	Yes	Yes
Standard met	IEC 60601-1, IEC60601-1-2, IEC 80601-2-60, IEC 62471	CAN/CSA C22.2 No.601.1-M90, EC 93/42/EEC, IEC 60601-1, IEC60601-1-2, UL60601-1
Thermal safety	When in use, the LEDs of the Qraypen may generate surface temperature up to 133°F (56°C). To avoid the potential risk of burn, do not use the Qraypen continuously (Operating cycle: 50 s activation (on) time/1 min deactivation (off) time). As an additional safety measure, the Qraypen is equipped with a sleep mode feature. This feature turns off the LEDs in the Qraypen automatically after 2 minutes of continuous use. The LEDs can be turned back on by simply pressing any buttons on the handpiece.	When in use, the LEDs in the CDR-CAM may generate surface temperatures in excess of 106°F (41°C). To avoid the potential risk of burn, do not use the CDR-CAM in a single hand-held position for a prolonged period. As an additional safety measure, the CDR-CAM is equipped with an Auto-Off feature. This feature turns off the camera automatically after 5 minutes of continuous use. The camera can be turned back on by simply pressing the ON/OFF button on the handpiece.

7. Summary of Non-Clinical Performance Testing

The following performance data were provided to support the substantial equivalence determination.

Non-Clinical Testing

Non-clinical tests relied on this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- **Electromagnetic Compatibility (EMC) Testing**

  IEC 60601-1-2:2014, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

- **Electrical Safety Testing**

  IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

  IEC 80601-2-60:2012, Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

- **Software Verification and Validation**

  Software documentation for moderate level of concern was provided per the FDA Guidance for Software Contained in Medical Devices

- **Photobiological Safety Testing**

  IEC 62471:2006, Photobiological safety of lamps and lamp systems

- **Cleaning and Disinfection Validation**

  Cleaning and disinfection validation were conducted per the FDA Guidance Document for Reprocessing of Medical Devices.

- **Biocompatibility Testing**

  No biocompatibility testing was conducted.
  - No part of this device comes into contact with the patient's body directly or indirectly.
  - A Disposable sleeve covers the camera and provides a sanitary shield for the patient.

- **Bench Testing**

Bench testing was conducted to demonstrate appropriate output with an FDA cleared barrier sleeve over the device.

- **Animal Study**

No animal studies were conducted.

8. Conclusion

In accordance with the above data and based on the information provided in this premarket notification AIOBIO Co., Ltd. concludes that the Qraypen is substantially equivalent to CDR-CAM of SCHICK TECHNOLOGIES, INC. in terms of design, performance, technological characteristics, and indications for use as described herein.

END