September 4, 2024

Aiobio Co., Ltd.
% Jeongkeun Kim
Regulatory Affairs Consultant
KMC,Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
Korea, South

Re: K221275
Trade/Device Name: Qraycam PRO
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NBL
Dated: August 6, 2024
Received: August 6, 2024

Dear Jeongkeun 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K221275

Device Name

Qraycam PRO

Indications for Use *(Describe)*

The Qraycam PRO is intended to be used as an aid in the 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K221275

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Aug 06, 2024

1. Applicant / Submission Sponsor

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2. Submission Correspondent

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3. Device Identification

Trade/Proprietary Name: Qraycam PRO
Common Name: Laser, Fluorescence Caries Detection
Classification Regulation: 21CFR 872.17445
Product Code: NBL
Device Class: 2

4. Predicate Devices

	Predicate Device #1
Manufacturer	INSPEKTOR DENTAL CARE BV
Device Name	INSPEKTOR™ PRO
510(k) number	K040063

5. Description

Qraycam PRO is a fluorescence caries detection aid, designed to assist dentists and dental specialists in identifying caries areas during oral health examinations.
The device produces images that can be displayed on an LCD screen attached to the main body or on a computer monitor.

- ✓ Integral LED that allows the LED to be changed without detaching the body tube
- ✓ Ease of use with automatic focusing
- ✓ Images can be captured and saved in electronic charts and insurance claims programs

6. Indications for use

The Qraycam PRO is intended to be used as an aid in the diagnosis of dental caries.

7. Substantial Equivalence

Qraycam PRO is substantially equivalent to the predicate devices (InspektorTM Pro, K040063). The following table is presented to demonstrate substantial equivalence.

	Subject Device	Predicate Device
Manufacturer	AIOBIO CO.,LTD	INSPEKTOR DENTAL CARE BV
Device Name	Qraycam PRO	INSPEKTOR™ PRO
510(k) number	-	K040063
Classification Product Code / Regulatory Number	NBL 872.1745	NBL 872.1745
Regulatory Class	Class II	Class II
Indications for Use	The Qraycam Pro is intended to be used as an aid in the diagnosis of dental caries.	The InspektorTM Pro is intended to be used as an aid in the diagnosis of dental caries.
Prescription or OTC	Prescription use	Prescription use
Operation	The lens and LED lights mounted on the body tube of the device can be used with a special filter to illuminate the oral cavity and check the state of the patient's oral health. This caries detection device contains its own light source and is used through connection to a desktop PC or laptop in dentistry.	The Inspektor Pro intra-oral camera consists of a control box that is connected via a liquid light guide and electrical cable to the camera handpiece. The control box contains a 35W arc lamp with a violet-blue band-pass filter in front of it. Light passing through the filter is coupled into a liquid light guide for delivery to the tooth surfaces, exposing them to blue light. The thus obtained fluorescence images can be visualised on a monitor real-time, using the miniature CCD camera inside the handpiece. Using the Inspektor Pro software images can easily be captured, stored and analysed
Technology	QLF-D	QLF-D

Image sensor		- 2.1Megapixel image sensor - CMOS Video image sensor	- 1/4-inch colour CCD sensor
Resolution		- LCD: 3.5inch hdmi monitor Signal Input Port: hdmi 1920x1080 60p Physical resolution: 320*480 Adjustable resolution: 320x480 - 1920x1080 Play video: 60Fps high speed support	Play video: 480p ~ 1080p, 50Fps speed support
LENS	Type	Variable focus Liquid LENS	Single LENS Panasonic video camera
	Focus	Trigger AF (50mm ~ 200mm)	N/A
	Focal length	7.5 mm	None
	F number	2.9	None
	Back Focal Length	4.07	None
Light Source	White	4EA White chip LED	None
	Blue	12EA UV chip LED	Short-arc micro-discharge XENON with blue band pass filter
Light wavelength		405 nm (min: 365nm, max: 410nm)	404 nm
Light Power	White	3.3W (3.3V, 1000mA)	-
	Blue	1.47W (3.2V-4.2V, 350mA)	35 W
Interface		PC USB 2.0	PC USB 2.0
Image analysis		Qraycam PRO software	INSPEKTOR PRO software
Single-use		Reusable	Reusable

Technical Characteristics

1) Same Points between subject device and predicate device

Item	Description
Product Code	The proposed product code of the subject device is NBL for fluorescence caries detection aid device function. It is the same product code as the predicate device in K040063.
Regulatory number and classification	The proposed regulatory number of the subject device is 872.1745 and the classification is Class II. It is same regulatory number and classification as the predicate device in K040063.
Indications for Use	The subject device is indicated for use in dental diagnosis procedures for detecting the dental caries using a fluorescence technology (QLF-D technologies).
Technology	The same of technology, QLF-D technology to detect caries using a light energy delivered to the teeth.

Item	Description
	The Quantitative light-induced fluorescence (QLF-D) technology is with QLF-D the green auto-fluorescence of tooth structures and the red fluorescence of bacterial metabolites can be assessed.
Light source	The similar method of lighting energy delivered to teeth as UV LED(blue light).
Blue light wavelength	Images are obtained by illuminating the oral cavity with the blue light (Wavelength 405nm) and filter. And also, images can be analyzed to quantify the dental caries stages by dedicated software.
Single Use / Reusable	The subject device is reusable. It is same with the predicate device.

2) Different Points between subject device and predicate device

Item	Description
Light source	The subject device has difference Light source about white LED. White LED is used for the purpose only of illumination and better focusing in the oral cavity. And also, we performed photobiological safety of lamps (LED) test complied with IEC 62471.
Oral camera type	The subject device is an Outral Oral Camera, whereas the predicate device is an Intral Oral Camera, presenting some differences. However, both devices share the same intended use and similar technology, allowing for the identification of dental caries at an equivalent level within a limited intraoral scope. Additionally, the manufacturer has specified in the user manual: "Please do not use the device on teeth where visual identification is difficult due to malocclusion." Therefore, it has been confirmed that there is no significant difference in clinical safety regarding the use and intended purpose of the products.

8. Performance data

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

Non-clinical performance data

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 disturbances - Requirements and tests

- Electrical Safety Testing

  IEC 60601-1:2005+A1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

  IEC 80601-2-60:2019, Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

- Software Verification and Validation

  IEC 62304:2015, Medical Device Software - Software Life Cycle Processes

- Photobiological Safety Testing

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

- Non-clinical Bench test

  The manufacturer conducted a comparative performance evaluation through bench tests to confirm that there are no significant differences in clinical and intended use outcomes between the Outral Oral Camera and the predicate Intral Oral Camera under the same conditions and using the same teeth.

  As a result, the ΔF average value, the performance criterion, was found to meet the standard, confirming the clinical performance equivalence of the product.

- Biocompatibility Testing

  No biocompatibility testing was conducted.

  - No part of this device comes into contact with the patient's body directly or indirectly.

9. Conclusion

In comparing between the subject device and the predicate device, there are the same Product code, Regulatory number, Classification, Indications for Use, Technology, Light source, Blue light wavelength, IEC 60601-1, IEC 60601-1-2, IEC 62471 and ISO 14971.

Although the Light source and Oral camera type are difference, these differences do not raise different questions of safety and effectiveness.

Therefore, the subject device is substantially equivalent to the predicate device.