December 17, 2024

AI Optics
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K243664
Trade/Device Name: Sentinel Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: November 27, 2024
Received: November 27, 2024

Dear Prithul Bom:

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,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic 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.

510(k) Number *(if known)*
K243664

Device Name
Sentinel Camera

Indications for Use *(Describe)*
Sentinel Camera is a non-mydriatic medical digital camera that is intended to capture digital images of the human eye.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Sentinel Camera 510(k) Summary (K243664)

510(k) Submitter:	AI Optics
Address:	145 Lexington Ave Floor 10 New York, New York 10016
Company Phone:	914-874-3256
Contact Person:	Andrew DiGiore
Date:	December 16, 2024

Subject Device:	Trade Name:	Sentinel Camera
	510(k) Number:	K243664
	Common Name:	Ophthalmic Camera
	Classification Name:	Camera, Ophthalmic, AC-Powered (21 CFR 886.1120)
	Regulatory Class:	II
	Product Code:	HKI
Predicate Device:	Trade Name:	Optomed Aurora Camera Optomed Aurora Retinal Module Optomed Aurora Anterior Module
	510(k) Number:	K180378
	Regulatory Class:	II
	Product Code:	HKI

Description of the Device

The Sentinel Camera is accompanied by the following accessories: a charging base, eye cup, and power cable.

The Sentinel Camera is designed for use in a medical environment. Captured images are used for documentation and consultation. Sentinel Camera has internal memory where captured images are stored.

The Sentinel Camera is designed for non-mydriatic retinal imaging. In non-mydriatic imaging no mydriasis is needed because infrared light is used for targeting the retina and white light is flashed when an image is taken. The pupil does not respond to the infrared light, so examination is convenient for the patient. With small pupils, it is recommended to use mydriatic drops. The Sentinel Camera has three internal fixation targets for the patient to fixate on during imaging. The middle fixation target provides a macula-centered image. The left and right fixation targets provide disc-centered images.

The transfer of images to the AI Optics Server is carried out via Wi-Fi communication.

The Sentinel Camera has a rechargeable Li-ion battery that is charged when the camera is placed on charging base, which is connected to the mains by the power cable.

Indications for Use

Sentinel Camera is a non-mydriatic medical digital camera that is intended to capture digital images of the human eye.

Comparison of Technological Characteristics

The technological characteristics of the Sentinel Camera closely match those of the Optomed Aurora Camera Optomed Aurora Retinal Module Optomed Aurora Anterior Module (K180378). Both devices utilize similar imaging technology, including a high-resolution camera and light sources for illumination. The slight variations in specifications does not raise new questions of safety and effectiveness.

Table 1 below includes a summary of the technical information used in the substantial equivalence discussion.

Table 1: Substantial Equivalence

Characteristic	Subject Device	Predicate Device
Device Name	Sentinel Camera	Optomed Aurora Camera Optomed Aurora Retinal Module Optomed Aurora Anterior Module
510(k) Number	K243664	K180378
Classification	HKI	HKI
Device Class	Class II	Class II
CFR Section	21 CFR 886.1120	21 CFR 886.1120
Common Name	Ophthalmic camera	Ophthalmic camera
Indication for Use	Sentinel Camera is a medical digital camera that is intended to capture images of the eye.	Optomed Aurora Camera is a medical digital camera that is used with dedicated optics modules intended to capture images and videos of fundus of the eye and surface of the eye. Optomed Aurora Camera with Optomed Aurora Retinal Module is intended to capture digital images and videos of the human eye. Optomed Aurora Camera with Optomed Aurora Anterior Module is intended to capture digital images and video of the surface of the human eye and surrounding areas.
Usage	Prescription Use	Prescription Use
Use Condition	Intended to be used without mydriasis but can be used also with mydriatic drops.	Intended to be used without mydriasis but can be used also with mydriatic drops.
Patient Population	System is not patient population specific.	System is not patient population specific.

Illumination Source	• White: OSRAM Oslon Compact PL • IR: Roithner Lasertechnik SMB1N • Target LEDs: Kingbright	Aurora Retinal Module: • White: OSRAM Oslon LUWH9GP • NIR: OSRAM Oslon SFH-4716 • Target LEDs: Vishay VLMS1500-GS08 Aurora Anterior Module: • White: OSRAM Advanced Power Topled LW G6SP-EAFS-JKQL-1 • Blue: OSRAM Advanced Power Topled LB G6SP-V2BB-35-1
Display System	4.0”, TFT-LCD, 720x720 pixels	4.0’’, TFT-LCD, 800x480 pixels
Camera Sensor	Color CMOS camera maximum resolution 5 MP	Color CMOS camera maximum resolution 5 MP
Diopter Compensation	From -20 D to +15 D	From -20 D to +20 D
Field of View	50 x 40 degrees	50 x 40 degrees
Storage Media	Internal storage	MicroSDHC memory card
Image Data Format	PNG	JPEG, MPEG-4
Weight	900 g	Aurora Camera: 514g Aurora Retinal Module: 310g Aurora Anterior Module: 105g
Battery	Rechargeable Li-Ion battery, 3.65 V, 5200 mAh	Rechargeable Li-Ion battery, 5000065, 3.63 V, 2600 mAH
Data Transfer	Data transfer via Wi-Fi	Data transfer via USB (1.1)
Standards	• IEC 60601-1:2005+A2:2020 (Edition 3.2) • IEC 60601-1-2: 2014 +A1: 2020 (Edition 4.1) • ISO 15004-1:2020 • ANSI Z80.36:2016 • ISO 10940:2009 • NEMA PS3.1-30.20: 2021 • IEC 62304:2015 • ISO 10993-1:2018 • NEMA PS 3.1 - 3.20 2022 • NEMA PS 3.1 - 3.20 2023	• IEC 60601- 1:2005+A1:2012 (Edition 3.1) • IEC 60601-1-2:2014 (Edition 4.0) • IEC 60601-1- 6:2010+A1:2013 (Edition 3.1) • IEC 62471:2006 • ISO 15004-1:2006 • ISO 15004-2:2007 • ISO 10940:2009 • IEC 62304:2006 +A1:2015 • IEC 62366-1:2015

Performance Data

Performance data for the Sentinel Camera, including extensive testing against recognized standards, supports the substantial equivalence of the Sentinel Camera to the predicate device. Both devices underwent similar testing to external standards. The testing demonstrates that the Sentinel Camera meets

the necessary safety and performance criteria, with no new questions of safety or effectiveness raised by the differences in technological characteristics, therefore supporting the conclusion of substantial equivalence.

Conclusion

Based on the provided performance data and the comparison, Sentinel Camera is as safe, as effective, and performs as well as or better than the predicate device. Sentinel Camera is substantially equivalent to the predicate device.