April 5, 2018

Optomed Oy
Jyri Leskela
Quality Manager
Yrttipellontie 1
Oulu, 90230 Fi

Re: K180378
Trade/Device Name: Optomed Aurora Camera with Aurora Retinal Module and Aurora Anterior Module
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: January 31, 2018
Received: February 12, 2018

Dear Jyri Leskela:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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)*

K180378

Device Name
Optomed Aurora Camera
Optomed Aurora Retinal Module
Optomed Aurora Anterior Module

Indications for Use *(Describe)*

Optomed Aurora Camera is a medical digital camera that is used with dedicated optics modules intended to capture images and video of the fundus of the eye and surface of the eye.

Optomed Aurora Camera with Optomed Aurora Retinal Module is intended to capture digital images and video of the fundus 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.

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.

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510(k) Summary

510(k) submitter:	Optomed Oy
Address:	Yrttipellontie 1, FI-90230 Oulu, Finland
Company phone:	+358 20 741 3380
Contact person:	Mr. Jyri Leskelä, Quality Manager
Date:	April 4, 2018

Subject device:	Trade name:	Optomed Aurora Camera Optomed Aurora Retinal Module Optomed Aurora Anterior Module
	510(k) number:	K180378
	Common/usual name:	Ophthalmic camera
	Classification name:	camera, ophthalmic, ac-powered (21 CFR 886.1120)
	Regulatory Class:	II
	Product Code:	HKI

Predicate device:	Trade name:	Optomed Smartscope M5 digital camera Optomed Smartscope EY4 optics module Optomed Smartscope ES2 optics module
	510(k) number:	K132186
	Regulatory Class:	II
	Product code:	HKI

Description of the Device

Optomed Aurora device set for ophthalmic imaging consists of Optomed Aurora Camera, Optomed Aurora Retinal Module and Optomed Aurora Anterior Module with following accessories Optomed Aurora Charging Station, USB cable, power supply, eye cups (2 pcs), batteries (2 pcs), USB flash drive and cleaning cloth.

Optomed Aurora Camera is designed for use in a medical environment. Captured images and video are used for documentation and consultation. Optomed Aurora Camera has a memory card where captured images and recorded videos are saved. Optomed Aurora Camera is used with interchangeable optics modules Optomed Aurora Retinal Module and Optomed Aurora Anterior Module. Optics modules are attached to the camera with bayonet connectors.

Optomed Aurora Retinal Module is designed for non-mydriatic fundus imaging. In non-mydriatic imaging no mydriasis is needed because infrared light is used for targeting the fundus 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. Optomed Aurora Retinal Module has nine internal fixation targets for the patient to fixate on during imaging. The middle fixation target provides a macula-centered image. The material of the eye cup is Momentive LIM 6030AB.

Optomed Aurora Anterior Module has two light sources for imaging eye surface and surrounding areas: white and cobalt blue. Cobalt blue light enables capturing of fluorescent images. There are four focus windows to focus the image. The material of the eye cup is Momentive Silopren LSR 4040.

Optomed Aurora Camera has a WLAN module inside and when WLAN is used, Optomed Aurora Camera transfers captured images and recorded videos to the PC automatically immediately after imaging. Images and videos can also be transferred to PC from the memory card when the camera is placed on Optomed Aurora Charging Station and the USB cable is connected between Optomed Aurora Charging Station and the PC. The image data transfer method to PC is similar as with any other USB mass storage device.

Optomed Aurora Camera has a rechargeable Li-ion battery that is charged when the camera is placed on Optomed Aurora Charging Station, which is connected to the mains by power supply cable. Optomed Aurora Charging Station can also be used as an external battery charger for the spare battery included in sales case. When Optomed Aurora Camera is not used, it may be stored on Optomed Aurora Charging Station. Storing the device on Optomed Aurora Charging Station is not harmful for the battery.

Indications for Use

Optomed Aurora Camera is a medical digital camera that is used with dedicated optics modules intended to capture images and video of the fundus of the eye and surface of the eye.

Optomed Aurora Camera with Optomed Aurora Retinal Module is intended to capture digital images and video of the fundus 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.

Optomed Aurora is classified as prescription device. Federal law restricts this device to sale by or on the order of a physician or licensed practitioner. The device may only be operated by persons who have been properly trained or who have the required knowledge and experience to do so. The device may only be used in accordance with its intended use.

The operating principle and the intended use of Optomed Aurora Camera with Optomed Aurora Retinal Module and Optomed Aurora Anterior Module are the same than Smartscope M5 camera with Smartscope EY4 optics module and Smartscope ES2 optics module. There are incremental changes in mechanics, software, hardware and optics. These changes do not affect safety and effectiveness of the product.

Comparison of Technological Characteristics

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

Table 1. Summary of technical information used in the substantial equivalence discussion.

Point of comparison	Optomed Aurora Camera Optomed Aurora Retinal Module Optomed Aurora Anterior Module	Optomed Smartscope M5 Optomed Smartscope EY4 Optomed Smartscope ES2
510(k) number	K180378	K132186
Indications of use	**Optomed Aurora Camera** is a medical digital camera that is used with dedicated optics modules intended to capture images and video of the fundus of the eye and surface of the eye.	**Optomed Smartscope M5** is a medical digital camera that is used with dedicated optics lens intended to take images of the eye fundus and surface of the eye.

	Optomed Aurora Camera with **Optomed Aurora Retinal Module** is intended to capture digital images and video of the fundus 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.	Optomed Smartscope M5 digital camera with **Smartscope EY4** optics module is intended to capture digital images and video of the fundus of the human eye. Optomed Smartscope M5 digital camera with **Smartscope ES2** optics module is intended to capture 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.
Illumination source	**Aurora Retinal Module:** White: OSRAM Oslon LUW-H9GP NIR: OSRAM Oslon SFH-4716 Target LEDs: Vishay VLMS1500 - GS08 **Aurora Anterior Module:** White: Osram Advanced Power Topled LW G6SP-EAFA-JKQL-1 Blue: Osram Advanced Power Topled LB G6SP-V2BB-35-1	**Smartscope EY4:** White: OSRAM Oslon LUW-H9GP NIR: OSRAM Oslon SFH-4715 Target LEDs: OSRAM LR QH9F **Smartscope ES2:** White: Osram Advanced Power Topled LW G6SP-EAFA-JKQL-1 Blue: Osram Advanced Power Topled LB G6SP-V2BB-35-1
Display system	4.0'', TFT-LCD, 800x480 pixels, 16.7 M colors, anti-glare coating	2.4'', TFT-LCD, 240x320 pixels, 262 000 colors, antireflective coating
Camera sensor specification	Color CMOS camera maximum resolution 5 Mp	Color CMOS camera maximum resolution 5 Mp
Diopter compensation	From -20 D to +20 D	At least from -20 D to +20 D
Field of view	50x40 degrees	40 degrees
Storage media	MicroSDHC memory card	MicroSDHC memory card
Image data format	JPEG, MPEG-4	JPEG, MPEG-1, MPEG-4
Weight	Aurora Camera: 514 g Aurora Retinal Module: 310 g Aurora Anterior Module: 105 g	Smartscope M5: 400g Smartscope EY4: 300g Smartscope ES2: 90 g

Battery	Re-chargeable Li-Ion battery, 50000655, 3.63 V, 2600 mAh	Re-chargeable Ni-MH battery, HR4U700AAA, 4.8V, 1000 mAh
Output terminals and data collection	USB (1.1) terminal (B-connector). Compatible with Windows® 7/8.1/10 and macOS (three latest versions).	USB (1.1) terminal (B-connector). Compatible with Windows® 7/8.1/10.
Exposure parameters	"Exempt Group" (no risk) LED product according to IEC 62471:2006 Group 2 instrument according to ISO 15004-2:2007	"Exempt Group" (no risk) LED product according to IEC 62471:2006 Group 2 instrument according to ISO 15004-2:2007
Standards	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 ISO 10993-5:2009 IEC 62304:2006+A1:2015 IEC 62366-1:2015	IEC 60601-1:2005+A1:2012 (edition 3.1) IEC 60601-1-2:2007 (edition 3.0) IEC 60601-1-6:2010+A1:2013 (edition 3.1) IEC 62471:2006 ISO 15004-1:2006 ISO 15004-2:2007 ISO 10940:2009 ISO 10993-5:2009 IEC 62304:2006+A1:2015 IEC 62366-1:2015

The modifications in Optomed Aurora Camera with Optomed Aurora Retinal Module and Optomed Aurora Anterior Module compared to Optomed Smartscope M5 with Optomed Smartscope EY4 optics module and Optomed Smartscope ES2 optics module are:

Aurora Camera:

- New industrial design
- New user interface: rotary encoder, capacitive touch buttons, battery charging indicator LEDs
- Improved, larger display
- New battery
- Improved WLAN functionality
- New GUI (graphical user interface with new colors, fonts and structure)

Aurora Retinal Module:

- New industrial design
- Increased FOV (field of view)
- Higher image resolution

Aurora Anterior Module

- New industrial design

Aurora Charging Station

- New industrial design
- External battery charger

Performance Data

The following performance data is provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

Optomed Aurora Camera with Optomed Aurora Retinal Module and Optomed Aurora Anterior Module was tested according to all suitable clauses of IEC 60601-1:2005+A1:2012 (safety) and IEC 60601-1-2:2014 (EMC). Optomed Aurora Camera with Optomed Aurora Retinal Module and Optomed Aurora Anterior Module fulfills the requirements of the standards.

Optical safety

Optomed Aurora Retinal Module and Optomed Aurora Anterior Module were tested according to the standard IEC 62471:2006 and are classified as “Exempt Group” (NO RISK) LED products.

Optomed Aurora Retinal Module and Optomed Aurora Anterior Module were tested according to the standard ISO 15004-2:2007 and are classified as Group 2 ophthalmic instruments.

Software Verification and Validation

The level of concern of the software is moderate. Software verification and validation were conducted to ensure the fulfillment of the system requirements and functional specifications. Optomed Aurora Camera with Optomed Aurora Retinal Module and Optomed Aurora Anterior Module complies with the standard IEC 62304:2006+A1:2015.

Environmental testing

Optomed Aurora Camera with Optomed Aurora Retinal Module and Optomed Aurora Anterior Module was tested according to ISO 15004-1:2006, IEC 60601-1 and IEC 60068-2 standards to verify the mechanical stress and ambient conditions for use and storage as prescribed for the device. The devices fulfill the requirements of the standard. In addition, Optomed Aurora Camera with Optomed Aurora Retinal Module and Optomed Anterior Module was tested according to IEC 60068-2 for high temperature, low temperature, shock, vibration and bump to verify transportation conditions.

Biocompatibility

Optomed Aurora Retinal Module and Optomed Aurora Anterior Module have an eye cup that contacts skin around eye during normal usage of the device. The material of Optomed Aurora Retinal Module eye cup is Momentive LIM 6030AB and the material of Optomed Aurora Anterior Module eye cup is Momentive Silopren LSR 4040. In vitro cytotoxicity tests according to ISO 10993-5:2009 were performed to the materials of the eye cups, and the biocompatibility of Optomed Aurora Retinal Module and Optomed Aurora Anterior Module are at suitable level.

Optical performance

Aurora Camera with Aurora Retinal Module fulfills the requirements of the standard ISO 10940:2009 Ophthalmic instruments - Fundus cameras.

Usability (Human Factors)

Optomed Aurora Camera with Optomed Aurora Retinal Module and Optomed Aurora Anterior Module was designed and evaluated by following the principles depicted in the usability engineering process. The usage of Optomed Aurora Camera with Optomed Aurora Retinal Module and Optomed Aurora Anterior Module was evaluated to be suitable for its intended use and the devices complies with the standards IEC 60601-1-6:2010+A1:2013 and IEC 62366-1:2015.

Conclusions

Based on the provided performance data and the comparison, Optomed Aurora including Optomed Aurora Camera, Optomed Aurora Retinal Module and Optomed Aurora Anterior Module, is as safe, as effective and performs as well as or better than the predicate device. Optomed Aurora is substantially equivalent to the predicate device.