Optomed Oyj
Jyri Leskelä
Director Q&RA
Yrttipellontie 1
Oulu, 90230
Finland

Re: K201325
Trade/Device Name: Optomed Smartscope M5 with Optomed Smartscope FA
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: May 7, 2020
Received: May 18, 2020

Dear Jyri Leskelä:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201325

Device Name
Optomed Smartscope M5
Optomed Smartscope FA

Indications for Use *(Describe)*
Optomed Smartscope M5 digital camera with Smartscope FA optics module is intended to capture fluorescein angiograms 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."

510(k) Summary

510(k) submitter:	Optomed Oyj	
Address:	Yrttipellontie 1, FI-90230 Oulu, Finland	
Company phone:	+358 20 741 3380	
Contact person:	Mr. Jyri Leskelä, Quality and Regulatory Director	
Date:	October 15, 2020	
Subject device:	Trade name:	Optomed Smartscope FA
	Common/usual name:	Ophthalmic camera
	Classification name:	camera, ophthalmic, ac-powered (21 CFR 886.1120)
	Regulatory Class:	II
	Product Code:	HKI
Predicate device: (Primary)	Trade name:	Optomed Smartscope M5 digital camera Optomed Smartscope EY4 optics module
	510(k) number:	K132186
	Regulatory Class:	II
	Product code:	HKI
Predicate device:	Trade name:	Kowa Genesis Df
	510(k) number:	K091098
	Regulatory Class:	II
	Product code:	HKI

OPTOMED OYJ | Yrttipellontie 1, 90230 Oulu, Finland
TEL: +358 20 741 3380 | info@optomed.com | www.optomed.com

Description of the Device

Optomed Smartscope M5 camera with Smartscope FA optics module is designed for use in a medical environment. Captured images and video are used for documentation and consultation. Optomed Smartscope M5 camera has a memory card where captured images and recorded videos are saved. Optomed Smartscope M5 camera is used with interchangeable optics modules previously cleared Smartscope EY4 and Smartscope ES2 and subject device Smartscope FA. Optics modules are attached to the camera with bayonet connectors.

Optomed Smartscope FA optics module is designed for fundus fluorescein angiography imaging of the human eye. Optomed Smartscope FA optics module includes two light sources: Blue light and infrared light, optical component that reflects light to the optical path and lenses that guide light through the pupil to the back of the eye and back to the camera sensor. Optomed Smartscope FA optics module has nine internal fixation targets for the patient to fixate on during imaging. Optomed Smartscope FA optics module receives power from Optomed Smartscope M5 digital camera.

Optomed Smartscope M5 camera has a WLAN module inside and when WLAN is used, Optomed Smartscope M5 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 Charging Station and the USB cable is connected between Charging Station and the PC. The image data transfer method to PC is similar as with any other USB mass storage device.

Optomed Smartscope M5 camera has a rechargeable Ni-MH battery that is charged when the camera is placed on Charging Station, which is connected to the mains by power supply cable. Charging Station can also be used as an external battery charger for the spare battery included in sales case. When Optomed Smartscope M5 camera is not used, it may be stored on Charging Station. Storing the device on Optomed Smartscope M5 camera Charging Station is not harmful for the battery.

OPTOMED OYJ | Yrttipellontie 1, 90230 Oulu, Finland
TEL: +358 20 741 3380 | info@optomed.com | www.optomed.com

Indications for Use

Optomed Smartscope M5 digital camera with Smartscope FA optics module is intended to capture fluorescein angiograms of the human eye.

Optomed Smartscope FA 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.

Optomed Smartscope M5 camera is modular and can be used together with dedicated optics modules (Smartscope EY4 and Smartscope FA) to capture images from the fundus of the eye. Predicate device Kowa Genesis Df is used to fundus imaging as well. Changes implemented to subject device Smartscope FA 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 Smartscope M5 Optomed Smartscope FA	Optomed Smartscope M5 Optomed Smartscope EY4	Kowa Genesis Df
510(k) number	K201325	K132186	K091098
Indications for use	Optomed Smartscope M5 digital camera with **Smartscope FA** optics module is intended to capture fluorescein angiograms of the human eye.	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.	A hand-held mydriatic retinal camera which captures fundus image (For color and FA retinal photography)
Usage	Prescription use	Prescription use	Prescription use
Use condition	Intended to be used with mydriatic drops.	Intended to be used without mydriasis but can be used also with mydriatic drops.	Intended to be used with mydriatic drops

OPTOMED OYJ | Yrttipellontie 1, 90230 Oulu, Finland
TEL: +358 20 741 3380 | info@optomed.com | www.optomed.com

Illumination source	**Smartscope FA:** Blue: Osram Oslon LB H9GP NIR: OSRAM Oslon SFH-4715 Target LEDs: OSRAM LR QH9F	**Smartscope EY4:** White: OSRAM Oslon LUW-H9GP NIR: OSRAM Oslon SFH-4715 Target LEDs: OSRAM LR QH9F	Observation light source: white LED / blue LED Photographing light source: Xenon flash lamp 23WS
Display system	2.4'', TFT-LCD, 240x320 pixels, 262 000 colors, antireflective coating	2.4'', TFT-LCD, 240x320 pixels, 262 000 colors, antireflective coating	Visual observation
Camera sensor specification	Color CMOS camera maximum resolution 5 Mp	Color CMOS camera maximum resolution 5 Mp	Color CCD camera 2,000,000 pixels
Diopter compensation	From -20 D to +20 D	At least from -20 D to +20 D	-15D~+35D
Field of view	40 degrees	40 degrees	Horizontal: 30 degree Vertical: 25 degree
Storage media	MicroSDHC memory card	MicroSDHC memory card	Flash memory card
Image data format	JPEG, MPEG-1, MPEG-4	JPEG, MPEG-1, MPEG-4	JPEG, uncompressed data
Weight	Smartscope M5: 400g Smartscope FA: 300g	Smartscope M5: 400g Smartscope EY4: 300g	Approx.1kg
Battery	Re-chargeable Ni-MH battery, HR4U700AAA, 4.8V, 1000 mAh	Re-chargeable Ni-MH battery, HR4U700AAA, 4.8V, 1000 mAh	Not battery-operated device
Output terminals and data collection	USB (1.1) terminal (B-connector). Compatible with Windows® 7/8.1/10.	USB (1.1) terminal (B-connector). Compatible with Windows® 7/8.1/10.	USB (1.1) terminal (B connector) Foot Switch connector cable terminal
Exposure parameters	“Exempt Group” (no risk) LED product according to IEC 62471:2006	“Exempt Group” (no risk) LED product according to IEC 62471:2006	N/A

OPTOMED OYJ | Yrttipellontie 1, 90230 Oulu, Finland
TEL: +358 20 741 3380 | info@optomed.com | www.optomed.com

	Group 1 instrument according to ANSI Z80.36-2016	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 ANSI Z80.36-2016 ISO 10940:2009 ISO 10993-5:2009 ISO 10993-10:2009 IEC 62304:2006+A1:2015 IEC 62366-1:2015	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 ISO 10993-10:2009 IEC 62304:2006+A1:2015 IEC 62366-1:2015	N/A

The modifications in Optomed Smartscope M5 camera with Smartscope FA optics module compared to Optomed Smartscope M5 camera with Optomed Smartscope EY4 optics module are:

Smartscope FA:

- Illumination source blue led
- Short pass filter in illumination path in front of blue led
- Barrier filter in imaging path
- Optical safety Group 1 tested according to ANSI Z80.36-2016

The differences in Optomed Smartscope M5 camera with Smartscope FA optics module compared to Kowa Genesis Df are:

Smartscope FA:

- Increased FOV (field of view)
- Higher image resolution

OPTOMED OYJ | Yrttipellontie 1, 90230 Oulu, Finland
TEL: +358 20 741 3380 | info@optomed.com | www.optomed.com

Performance Data

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

Electrical safety and electromagnetic compatibility (EMC)

Optomed Smartscope M5 camera with Smartscope FA optics module was tested according to all suitable clauses of IEC 60601-1:2005+A1:2012 (safety) and IEC 60601-1-2:2014 (EMC). Optomed Smartscope M5 camera with Smartscope FA optics module fulfills the requirements of the standards.

Optical safety

Optomed Smartscope M5 camera with Smartscope FA optics module was tested according to the standard IEC 62471:2006 and is classified as “Exempt Group” (NO RISK) LED products.

Optomed Smartscope M5 camera with Smartscope FA optics module was tested according to the standard ANSI Z80.36-2016 and is classified as Group 1 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 Smartscope M5 camera with Smartscope FA optics module complies with the standard IEC 62304:2006+A1:2015.

Environmental testing

Optomed Smartscope M5 camera with Smartscope FA optics 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 device fulfills the requirements of the standard. In addition, Optomed Smartscope M5 camera with Smartscope FA optics module was tested according to IEC 60068-2 for high temperature, low temperature, shock, vibration and bump to verify transportation conditions.

Biocompatibility

Optomed Smartscope FA optics module has an eye cup that contacts skin around eye during normal usage of the device. The material of Optomed Smartscope FA optics module eye cup is Momentive LIM 6030AB. In vitro cytotoxicity tests according to ISO 10993-5:2009 and Irritation and skin

OPTOMED OYJ | Yrttipellontie 1, 90230 Oulu, Finland
TEL: +358 20 741 3380 | info@optomed.com | www.optomed.com

sensitization tests according to ISO 10993-10:2009 were performed to the material of the eye cup, and the biocompatibility of Optomed Smartscope FA optics module is at suitable level.

Optical performance

Optomed M5 camera with Optomed Smartscope FA optics module fulfills the requirements of the standard ISO 10940:2009 Ophthalmic instruments - Fundus cameras.

Usability (Human Factors)

Optomed M5 camera with Optomed Smartscope FA optics module was designed and evaluated by following the principles depicted in the usability engineering process. The usage of Optomed M5 camera with Optomed Smartscope FA optics 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 M5 camera with Optomed Smartscope FA optics module, is as safe, as effective and performs similar to the predicate devices. Optomed M5 camera with Optomed Smartscope FA optics module is substantially equivalent to the predicate devices.

OPTOMED OYJ | Yrttipellontie 1, 90230 Oulu, Finland
TEL: +358 20 741 3380 | info@optomed.com | www.optomed.com