DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 11, 2017

Optomed Oy
Mr. Jyri Leskelä
Quality Manager
Yrttipellontie 1
Oulu, 90230 FI

Re: K163021
Trade/Device Name: HAAG-STREIT FUNDUS MODULE 300
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: February 23, 2017
Received: March 1, 2017

Dear Mr. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163021

Device Name
HAAG-STREIT FUNDUS MODULE 300

Indications for Use *(Describe)*
FUNDUS MODULE 300 is an ophthalmic camera that is used as an accessory with dedicated slit lamps to capture digital images and video of the fundus 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.

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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 6, 2017

Subject device:	**Trade name:**	HAAG-STREIT FUNDUS MODULE 300
	510(k) number:	K163021
	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 with Optomed Smartscope EY4 optics module
	510(k) number:	K132186
	Regulatory Class:	II
	Product code:	HKI

Description of the device

FUNDUS MODULE 300 device set for retinal imaging consists of FUNDUS MODULE 300 Camera with base plate, lens cover, battery and camera USB cable (0.6 m), and FUNDUS MODULE 300 Cradle with power supply and cradle USB cable (1.5 m). FUNDUS MODULE 300 is used with dedicated HAAG-STREIT slit lamps.

FUNDUS MODULE 300 is designed to be used in medical environment and it is intended for non-mydriatic imaging of the fundus of the human eye for documentation and consultation. In non-mydriatic imaging no mydriatic is needed because infrared light is used for the targeting image to the fundus and visible light is flashed when an image is taken. The pupil does not respond to the infrared light so examination is convenient for the patient. Constant white light illumination for targeting can be selected from device menu if mydriatic drops are used. Images can also be taken using infrared lightning for both aiming and capturing. The FUNDUS MODULE 300 has 9 internal fixation targets for the patient to fixate at during imaging. The middle fixation target provides a macula centred image.

FUNDUS MODULE 300 can be used together with HAAG-STREIT Release Module RM02 and HAAG-STREIT EyeSuite software. Controlling the FUNDUS MODULE 300 can be performed by Camera keys or by Release Module RM02. Captured images and recorded videos are automatically transferred to the PC (EyeSuite software) after imaging. Images and videos are stored on the micro SDHC memory card and can be also transferred to the PC by using Cradle USB connection. FUNDUS MODULE 300 Camera has rechargeable Li-Ion battery and the device is charged by using the Cradle.

Materials of outer shells of the FUNDUS MODULE 300 are plastic, aluminum and silicon. There is no applied parts (no parts which are designed to come into physical contact with the patient) in FUNDUS MODULE 300.

Indications for use

FUNDUS MODULE 300 is an ophthalmic camera that is used as an accessory with dedicated slit lamps to capture digital images and video of the fundus of the human eye.

FUNDUS MODULE 300 is classified as prescription device. Federal law restricts this device to sale by or on the order of a physician or licensed practitioner. This equipment must only be operated by qualified and trained personnel. The owner is responsible for the training. This device may only be used in accordance with intended use.

The operating principle and the intended use of the FUNDUS MODULE 300 is the same than Smartscope M5 with Smartscope EY4. The main difference between subject device and predicate device is that FUNDUS MODULE 300 is intended to be used as slit lamp accessory instead of being used as hand-held. There is incremental changes in mechanics, software and hardware. There is no changes in optics. These changes do not affect safety and effectiveness of the product.

Comparison of technological characteristics with the predicate device

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	**FUNDUS MODULE 300**	**Optomed Smartscope M5 with Smartscope EY4**
510(k) number	K163021	K132186
Indications of use	FUNDUS MODULE 300 is an ophthalmic camera that is used as an accessory with dedicated slit lamps to capture digital images and video of the fundus of the human eye.	Optomed Smartscope M5 digital camera with optics module Smartscope EY4 is intended to capture digital images and video of the fundus of the human eye.
Usage	Prescription use	Prescription use
Use condition	Intended to be used without mydriatic but can be used also with mydriatic.	Intended to be used without mydriatic but can be used also with mydriatic.
Observation light source	Visible and infrared LEDs: White: OSRAM Oslon LUW-H9GP NIR: OSRAM Oslon SFH-4715 Target LEDs: OSRAM LR QH9F	Visible and infrared LEDs: White: OSRAM Oslon LUW-H9GP NIR: OSRAM Oslon SFH-4715 Target LEDs: OSRAM LR QH9F
Observation and display system	3.97'', TFT-LCD, 800x480 pixels, 16.7 M colors, anti-glare coating	2.4'', TFT-LCD, active matrix color, antireflective coating
Photographing light source	Visible and infrared LED	Visible and infrared LED
Camera specification	Color CMOS camera maximum resolution 5 Mp. Optics uses 1.77 Mp.	Color CMOS camera maximum resolution 5 Mp. EY4 uses 1.77 Mp.
Diopter compensation	at least from –20 D to +20 D	at least from –20 D to +20 D

Picture angle	40 degrees	40 degrees
Storage media	MicroSDHC memory card	MicroSDHC memory card
Image data format	JPEG, MPEG-4	JPEG, MPEG-1, MPEG-4
Weight	1200 g	M5: 400g, EY4: 300g
Power consumption	Re-chargeable Li-Ion battery, NCA103450, 3.6 V, 2350 mAh	Re-chargeable Ni-MH Battery, HR4U700AAA, 4.8V, 1000 mAh; Charging unit 44 VA
Output terminals and data collection	USB (1.1) terminal (B-connector). Compatible with Windows® VISTA/7/8.1/10	USB (1.1) terminal (B-connector). Compatible with Windows® VISTA/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 EN 62471:2008 Group 2 instrument according to ISO 15004-2:2007
Standards	IEC 60601-1:2005 (edition 3.1) IEC 60601-1-2:2014 (edition 4.0) IEC 62471:2006 ISO 15004-1:2006 ISO 15004-2:2007 ISO 10940:2009 IEC 62366-1:2015	IEC 60601-1:2005 (edition 3.0) IEC 60601-1-2:2007 (edition 3.0) IEC 62471:2006 ISO 15004-1:2006 ISO 15004-2:2007 ISO 10940:2009 ISO 10993-5:2009

The modifications in FUNDUS MODULE 300 compared to Smartscope M5 with Smartscope EY4 optics are:

- **Mechanics**
  - FUNDUS MODULE 300 has new structure where camera and optics are integrated.
  - FUNDUS MODULE 300 has shaft: electronics and mechanics interface part to base plate.
  - FUNDUS MODULE 300 has base plate: mechanical interface part to slit lamp, electrical interface to medical PC.
- **Optics**
  - No changes.
- **SW**
  - FUNDUS MODULE 300 only supported optics is EY4.
  - FUNDUS MODULE 300 GUI is different: Display is larger with higher resolution (800x480). Colors and fonts differ.
  - FUNDUS MODULE 300 has no patient list support.
  - FUNDUS MODULE 300 can be controlled with Haag-Streit Release Module RM02.
  - FUNDUS MODULE 300 has slit lamp USB mode support: Images are transferred right after capture to the PC.
  - FUNDUS MODULE 300 is used together with Haag-Streit EyeSuite software.
- **HW**
  - FUNDUS MODULE 300 has camera board (main board, sensor board and AF board combined) and also shaft board and base plate board.
  - FUNDUS MODULE 300 battery is different (Li-ion)
  - FUNDUS MODULE 300 display is different
  - FUNDUS MODULE 300 cradle board is different
  - FUNDUS MODULE 300 AF module different

Performance data

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

Electrical safety and electromagnetic compatibility (EMC)
FUNDUS MODULE 300 was tested according to all suitable clauses of IEC 60601-1:2005+A1:2012 (safety) and IEC 60601-1-2:2014 (EMC). FUNDUS MODULE 300 fulfills the requirements of the standards.

Optical radiation safety
Smartscope EY4 was tested according to the standard ISO 15004-2:2007 (optical radiation safety) and FUNDUS MODULE 300 (identical to Smartscope EY4 optics module) is classified as Group 2 instrument.

Software Verification and Validation testing
The level of concern of software included in the FUNDUS MODULE 300 is moderate. Software verification and validation testing was conducted to ensure that design requirements and specified indications for use were fulfilled. FUNDUS MODULE 300 complies with standards IEC 60601-1-4:1996+A1:1999 and IEC 62304:2006+A1:2015.

Mechanic and environmental testing
FUNDUS MODULE 300 was tested according to all suitable clauses of IEC 60601 and IEC 60068. FUNDUS MODULE 300 fulfills the requirements of the standards.

Usability (Human factors)
FUNDUS MODULE 300 was designed according to the usability engineering process. FUNDUS MODULE 300 complies with standards IEC 60601-1-6:2010 and IEC 62366-1:2015.

Stability
FUNDUS MODULE 300 was tested for in use stability to correspond the expected life time of five years. Shipping stability was tested according to IEC 60068-2-27:2008.

Conclusions

Based on the comparison and supportive information, the FUNDUS MODULE 300 is substantially equivalent to the predicate device.