April 27, 2020

Optina Diagnostics
% Elisa Harvey
Principal Consultant
CardioMed Device Consultants LLC
1783 Forest Drive, #254
Annapolis, Maryland 21401

Re: K200254
Trade/Device Name: Mydriatic Hyperspectral Retinal Camera (MHRC-C1)
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI, NFJ
Dated: January 30, 2020
Received: February 3, 2020

Dear Elisa Harvey:

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,

Elvin Ng
Acting 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)*
K200254

Device Name
Mydriatic Hyperspectral Retinal Camera (MHRC-C1)

Indications for Use *(Describe)*
The Mydriatic Hyperspectral Retinal Camera (MHRC-C1) is intended to capture images of the retina at multiple wavelengths (colors) under mydriatic conditions.

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

APPLICANT:	Optina Diagnostics, Inc 7405 Route Transcanadienne, Suite #330 Montréal, Québec, Canada, H4T 1Z2 Phone : 514-394-0797
DATE PREPARED:	April 24, 2020
CONTACT PERSON:	Jean-Philippe Sylvestre
TRADE NAME:	Mydriatic Hyperspectral Retinal Camera (MHRC-C1)
COMMON NAME:	Fundus camera
REGULATION	Regulation Number: 21 CFR 886.1120 Regulation Name: Ophthalmic Camera Product Code: HKI, NFJ
DEVICE CLASSIFICATION:	Class 2
PREDICATE DEVICE (PRIMARY)	KOWA VX-20 (K112330)
REFERENCE DEVICE	Topcon TRC-50DX (K123101)

1. Device Description

The Mydriatic Hyperspectral Retinal Camera (MHRC-C1) is a mydriatic fundus camera (also called retinal camera) that presents eye care practitioners (optometrists and ophthalmologists) with a series of 92 images of the retina obtained sequentially at specific wavelengths (colors) in the spectral range 905 nm to 450 nm in steps of 5 nm.

Pictures of the retina are obtained on a field-of-view of 31.5° without contact with the eye. The patient is positioned in front of the device with the chin on the chinrest and forehead on the forehead rest and a positioning system is used to align the camera relative to the patient's eye. An external fixation target is available to guide the patient's eye. A focus wheel allows for the accommodation for eye refractive error in the range of -15 to +15

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diopters. The images are displayed on a monitor and can be saved on the computer for future consultation.

The illumination light of the MHRC-C1 is provided by a Tunable Laser Source (TLS). The TLS selects a narrow band of light from a broadband white illumination source. Only a single monochromatic band can output the TLS at a time. The alignment of the retinal camera relative to the patient's eye phase is performed with the illumination light set at a wavelength of 700 nm. The image acquisition phase consists of the sequential acquisition of a series of 92 monochromatic images at wavelengths from 905 nm to 450 nm in steps of 5 nm. Each frame is captured with an exposure time of 10 ms, resulting in a total acquisition time of 920 ms.

The 92 images can be visualized one by one in the MHRC-C1 acquisition software. The retinal images captured by the MHRC-C1 are monochromatic images having a spectral bandwidth of ~10 nm centered on the wavelength indicated in the upper left corner of the visualization pane, with a spectral accuracy of 7.5 nm.

2. Indications for Use

The Mydriatic Hyperspectral Retinal Camera (MHRC-C1) is intended to capture images of the retina at multiple wavelengths (colors) under mydriatic conditions.

3. Technological Characteristics:

The MHRC-C1 is similar in form and function to the predicate mydriatic fundus cameras (see Table 1 below). Indeed, the device is intended to obtain images of the retina with the use of a mydriatic. The contact areas of the patients are the same as for the predicate devices. The operator interface to perform retinal imaging is also similar to the predicate devices. Although there are differences in the technology to provide illumination of the retina, equivalent information may be inferred by scrolling through the monochromatic images obtained with the MHRC-C1 compared to what may be obtained in the color and red free monochrome imaging modes of the predicate devices. Performance testing was performed to verify that this technological difference raised no new concerns regarding the safety and efficacy of the device.

4. Performance Testing

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

Biocompatibility

The intact skin from the chin and forehead of the patient is intended to contact the MHRC-C1 for a short period of time. The biocompatibility of the MHRC-C1 was assessed in accordance with ISO 10993-1:2018.

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Software evaluation

The MHRC-C1 uses embedded Off-The-Shelf software. This software was evaluated for use in accordance with the FDA's Guidance for Industry "Off-The-Shelf Software use in Medical Devices" (September 1999) based on a "Moderate Level of Concern".

Electrical safety and electromagnetic compatibility

It was verified that the MHRC-C1 complies with the standard ANSI AAMI ES60601-1:2005/(R)2012+A1:2012 for electrical safety and with the standard IEC 60601-1-2:2014 for electromagnetic compatibility.

Evaluation of recognized consensus standards for ophthalmic cameras

The MHRC-C1 was found to comply with the recognized consensus standard ISO 15004-1:2006 specifying general requirements for ophthalmic instruments.

The MHRC-C1 was found to comply with the recognized consensus standard ISO 10940:2009 specifying product requirements for fundus camera.

The MHRC-C1 was found to comply with the recognized consensus standard ANSI Z80.36:2016 specifying fundamental requirements for optical radiation safety for ophthalmic instruments.

Spectral accuracy and reliability of the retinal images

The spectral accuracy of the illumination light of the MHRC-C1 was verified using a spectrometer.

The spectral accuracy and reliability of the retinal images were evaluated in an eye model using a reference material with tabulated spectral bands.

5. Substantial Equivalence

The MHRC-C1 is similar in form and function to the predicate and reference mydriatic fundus camera (see Table 1 below) and product testing was performed to demonstrate that the proposed device meets the recognized consensus standards related to a fundus camera. However, the MHRC-C1 uses "multiple wavelength (colors) imaging" which represents a hyperspectral feature that is a different technology in comparison to the proposed predicate device and reference device. Indeed, the technology to provide illumination of the retina in the proposed device consists in a tunable light source that sequentially present the retina with monochromatic light in the spectral range 905 nm to 450 nm in steps of 5 nm, while the predicate device and reference device use a xenon flash lamp with a broad white illumination spectrum. Despite this difference in technology, equivalent information may be inferred by scrolling through the monochromatic images obtained with the MHRC-C1 than what may be obtained in the color and red free monochrome imaging modes of the predicate and reference devices. Indeed, the images obtained with the MHRC-C1 cover the full visible spectral range that is covered in a color

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fundus image, typically composed of 3 broad spectral bands (red, green and blue) covering the spectral range 450 nm to 750 nm. Similarly, scrolling the images obtained with the MHRC-C1 in the spectral range corresponding to the green color (500-565 nm) covers the typical spectral range used to obtain retinal images in the red free mode. Moreover, the testing conducted to verify the spectral accuracy and repeatability of the proposed device supports that an image with the central wavelength corresponding to a specific color would display the features expected for an image in the spectral range corresponding to the expected color, thus preventing misinterpretation of the retinal images by the eye specialist due to an error in the displayed wavelength for a given retina image. It follows that the new feature of the proposed device, therefore, did not raise new concern regarding its safety and efficacy.

In conclusion, the performance testing supports that the MHRC-C1 meets the recognized consensus standards for a fundus camera and that retinal imaging at multiple wavelengths (colors) may be accurately and reliably achieved. The proposed device did not raise new concerns regarding its safety and efficacy for its intended use and was therefore deemed substantially equivalent to the predicate devices.

Table 1. Similarities and differences between the proposed device and the predicate device and reference device.

Device Name	**MHRC-C1**	**Kowa VX-20**	**TRC-50DX**
510(k) number	K200254	K112330	K123101
Regulation number	21 CFR 886.1120	21 CFR 886.1120	21 CFR 886.1120
Product code	HKI, NFJ	HKI, NFJ	HKI
Intended use	The MHRC-C1 is intended to capture images of the retina at multiple wavelengths (colors) under mydriatic conditions.	The device is intended for taking pictures of fundus images with mydriatic or without mydriatic	The TRC-50DX Retinal Camera is intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, with the use of a mydriatic
Camera function	Mydriatic	Mydriatic or non-mydriatic	Mydriatic
Photography type	Monochrome (92 color bands, 905 nm to 450 nm in steps of 5 nm)	Color Monochrome (Red free) Fluorescence Autofluorescence	Color Monochrome (Red free) Fluorescence Autofluorescence
Observation media	Video feed on LCD monitor	Video feed on LCD monitor or Optical viewfinder	Optical viewfinder
Record media	Digital	Digital	Digital or 35 mm film
Contact areas with the patients	Chin and forehead	Chin and forehead	Chin and forehead
Mean for alignment	Positioning base with joystick	Positioning base with joystick	Positioning base with joystick
Field of View	31.5 degrees	50 / 30 degrees	50 / 35 / 20 degrees
Working Distance	46.7 mm	39.0 mm	39.0 mm
Minimum pupil diameter	6 mm	5.5 mm (4.0 mm in non-mydriatic mode)	5.5 mm (4.5 mm in small pupil mode)

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Eye Fixation Navigation	External fixation target	External or internal fixation target	External or internal fixation target
Focusing	Focus wheel	Focus knob	Focus knob
Diopter compensation range of patient's eye	-15D to + 15D	-32D to + 35D	-23D to + 41D
Alignment/visualization light source	Monochromatic light (700 nm)	Halogen lamp	Halogen lamp
Photographing light source	Monochromatic light (sequential from 905 nm to 450 nm in steps of 5 nm)	Xenon lamp (flash)	Xenon lamp (flash)
Conformed performance standards	ISO 10940:2009 ISO 15004-1:2006 ISO15004-2:2007 ANSI Z80.36 IEC 60601-1-2:2014 ANSI AAMI ES60601-1::2005/(R)2012 and A1:2012	IEC 60601-1:1988 +A1:1991+A2:1995 IEC 60601-1-1:2007	IEC 60601-1-1:2001 ISO 15004-1:2006 ISO15004-2:2007