Optina Diagnostics Inc.
Sarah Lemaire
QA/RA Manager
8200 Decarie Boulevard
Montreal, QC H4P 2P5
Canada

Re: K231230
Trade/Device Name: Optina-4C (MHRC-C1N)
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: November 6, 2023
Received: November 7, 2023

Dear Sarah Lemaire:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231230

Device Name
Optina-4C (MHRC-C1N)

Indications for Use *(Describe)*
Optina-4C™ 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

APPLICANT:	Optina Diagnostics, Inc 8200 Decarie Blvd, Suite 220 Montreal (QC) H4P 2P5 Phone: 514-394-0797
ESTABLISHMENT REGISTRATION NUMBER	Registration Number: 3014606890 Owner Operator Number: 10081796
DATE PREPARED:	August 5, 2022
CONTACT PERSON:	Sarah Lemaire QA/RA Manager Email: slemaire@optinadx.com Phone: 579-421-0126
TRADE NAME:	Optina-4C™
MODEL:	MHRC-C1N
COMMON NAME:	Fundus camera
CLASSIFICATION NAME:	Camera, Ophthalmic, Ac-Powered (21 CFR 886.1120, Product Code HKI)
DEVICE CLASSIFICATION:	Class II
PREDICATE DEVICES	MHRC-C1 (K200254)

1. Description of the Modified Device

Optina-4C™ (model: MHRC-C1N) 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 diopters. The images are displayed on a monitor and can be saved on the computer for future consultation.

The illumination light of Optina-4C™ 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 Optina-4C™ acquisition software. The retinal images captured by Optina-4C™ 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

Optina-4C™ is intended to capture images of the retina at multiple wavelengths (colors) under mydriatic conditions.

3. Technological Characteristics

Optina-4C™ is similar in fit, form, and function to the predicate mydriatic fundus cameras. The main elements of the hardware including contact areas, the operator interface, the illumination of the retina, and the monochromatic images obtained with Optina-4C™ are the same as for the predicate device.

In comparison with the predicate device, Optina-4C™ has updated software and labeling and features network connectivity. 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.

- **Software evaluation**

  Optina-4C™ uses embedded Off-The-Shelf software and Software-of-Unknown-Provenance. This software was evaluated for use in accordance with the FDA's Guidance for Industry "Off-The-Shelf Software Use in Medical Devices" (September 2019) based on a "Moderate Level of Concern" and

IEC 62304:2006 + A1:2015 based on a ''Safety class B''.

- **Electrical safety and electromagnetic compatibility**

  It was verified that the Optina-4C™ 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**

  Optina-4C™ was found to comply with the recognized consensus standard ISO 15004-1:2020 specifying general requirements for ophthalmic instruments.

  The following performance data were conducted on the marketed device (MHRC-C1). No changes that can affect the evaluation or results of these recognized consensus standards were implemented on the Optina-4C™.

- **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.

- **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.

- **Evaluation of recognized consensus standards for ophthalmic cameras**

  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: 2021 specifying fundamental requirements for optical radiation safety for ophthalmic instruments.

5. Substantial Equivalence

In conclusion, the performance testing support that the Optina-4C™ 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 device.