September 4, 2025

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

Re: K250770
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: August 1, 2025
Received: August 4, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Alexander Beylin -S
Date: 2025.09.04 15:25:49 -04'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250770

Please provide the device trade name(s).

Optina-4C (MHRC-C1N)

Please provide your Indications for Use below.

Optina-4C™ is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying, storing, and transferring images of the retina. The Optina-4C is indicated for the viewing of the posterior segment of the eye at multiple wavelengths (colors) under mydriatic conditions.
Images are intended to aid clinicians in the detection, diagnosis, and management of ocular health and disease.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary K250770

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 1st, 2025
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-C1N (K231230) Camera, Ophthalmic, Ac-Powered (21 CFR 886.1120, Product Code HKI)

1. Description of the Modified Device

The Optina-4C™ (MHRC-C1N) is a non-contact mydriatic retinal camera (also called a fundus camera) designed to provide eye care professionals with a series of images of the retina obtained at specific wavelengths (colors). The Optina-4C processes images using algorithms that take advantage of the spectral information to produce 2D *en face* images of the retina as an aid to clinicians in the diagnosis of age-related macular degeneration (AMD), retinal pigment epithelium (RPE) disruptions and lesions, retinopathies, and other retinal diseases.

Utilizing Hyperspectral Imaging (HSI) technology, the Optina-4C captures a series of 92 high-resolution images at precise 5 nm wavelength increments across the visible and near-infrared (NIR) spectrum on a ~31° field-of-view. Image acquisition takes under two seconds, with only 0.92 seconds of light exposure time. During this time, the camera scans through all wavelengths from 905 to 450 nm, spending 10 milliseconds per 5 nm step.

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The Optina-4C processes the images to provide spectrally calibrated, normalized, and registered images in a structured Hyperspectral Cube format for scroll-through viewing. The spectral resolution supports visualization and differentiation of drusenoid deposit types, as well as high contrast viewing of the retinal chromophores hemoglobin, melanin, and carotenoids (combination of lutein and zeaxanthin). Images can be viewed, stored or transferred in their native .h5 format, or as DICOM or PNG formats. Optina-4C images offer sharp, vivid, high-contrast coronal views of the posterior segment of the eye for clinical assessment and evaluation by eye care professionals.

The HSI NormReg Cube is a processed data set of 91 hyperspectral images that have undergone intensity normalization and spatial registration. Normalization corrects for the non-uniform illumination profile of the imaging system and the spectral sensitivity of the camera, while registration compensates for intra-scan eye movement to ensure consistent alignment across frames. The result is a hyperspectral image cube with enhanced spatial and spectral fidelity, referred to as the HIS-NormReg Cube.

2. Indications for Use

Optina-4C™ is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying, storing, and transferring images of the retina. The Optina-4C is indicated for the viewing of the posterior segment of the eye at multiple wavelengths (colors) under mydriatic conditions. Images are intended to aid clinicians in the detection, diagnosis, and management of ocular health and disease.

3. Technological Characteristics

The table below contains a summary of the technological characteristics of the new version of the Optina-4C camera compared to the predicate device.

TRADE NAME	Optina-4C™		**SE discussion**
MODEL	MHRC-C1N		
510K number	K250770	K231230	
Energy source	Identical		N/A
Hardware components	Identical		N/A
Dimensions	Identical		N/A
Software components			
Network connectivity	Optina's Medical Device Data System (MDDS) used to transfer Images (h5 cubes) from Optina-4C system to either: - Optina PACS system (Azure) through a	N/A	**Equivalent** A security risk assessment has been conducted and demonstrated that no additional safety risks have been generated compared to the predicate device. The software verification and validation testing have been completed in accordance with our internal procedures for software validation and taking account the

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	SSH File Transfer Protocol (SFTP) - Customer local storage through a LAN connection - Customer PACS system through DICOM protocol		DICOM requirements.
Mean White Generator	Tool to adjust for illumination uniformity and intensity (mean white), internal reflection (mean baseline), and reading noise (mean dark).	N/A	**Equivalent** A security risk assessment has been conducted and demonstrated that no additional safety risks have been generated compared to the predicate device. The software verification and validation testing have been completed in accordance with our internal procedures for software validation
Operator Quality Feedback	Notify the operator if an artefact is detected in the acquired image. - Sensitivity: 84.39% - Specificity: 84.35%	N/A	**Equivalent** The software verification and validation testing have been conducted in accordance with the ISO 62304 standard and usability requirements. The documentation has been provided with this submission.
Optic nerve display	Display optic nerve target	N/A	**Equivalent** The software verification and validation testing have been conducted in accordance with the ISO 62304 standard and usability requirements. The documentation has been provided with this submission.
New retinal images	The following new images are generated: - NormReg - DeepRed - RedFree - RelSpec - Blue - RGB - HEM - MP	N/A	**Equivalent** The software verification and validation testing have been conducted in accordance with the ISO 62304 standard and usability requirements. The documentation has been provided with this submission.

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DICOM	Convert the file into a DICOM format.	N/A	**Equivalent** The DICOM converter software has been designed in compliance with the NEMA PS 3.1 - 3.20 standard. The software verification testing has been completed in accordance with the ISO 62304 standard and no additional safety risks have been generated compared to the predicate device. The documentation has been provided

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" (August 2023) 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, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] for electrical safety and with the standard IEC 60601-1-2: Edition 4.1 2020-09 CONSOLIDATED VERSION 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**

  Optina-4C™ was found to comply with the recognized consensus standard ISO 10940:2009 specifying product requirements for fundus camera.

  Optina-4C™ was found to comply with the recognized consensus standard ANSI Z80.36: 2021 specifying fundamental requirements for optical radiation safety for ophthalmic instruments.

- **Medical image management and processing system**

  Optina-4C™ was found to comply with the recognized consensus standard NEMA PS 3.1 - 3.20 2024 specifying product requirements Digital Imaging and Communications in Medicine (DICOM) Set.

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.