April 30, 2025

Optain Health, Inc.
℅ Maureen Oconnell
Regulatory Consultant
OConnell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K250683
Trade/Device Name: Resolve Fundus Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: March 6, 2025
Received: March 6, 2025

Dear Maureen Oconnell:

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,

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)*
K250683

Device Name
Resolve Fundus Camera

Indications for Use *(Describe)*
The Resolve Fundus Camera is an automatic eye-fundus camera intended for taking digital images of a human retina with or without the use of a mydriatic agent. It is intended for use as an aid to clinicians in the evaluation and diagnosis of ocular health.

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.

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"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

Optain Health, Inc.
Resolve™ Fundus Camera

510(k) Owner
Optain Health, Inc.
373 Park Avenue South
New York, NY 10016
Contact : Emilia Gonzalez
Telephone : 330-703-7443

Date Prepared: April 28, 2025

Trade Name of Device
Resolve™ Fundus Camera

Common or Usual Name
Ophthalmic Camera

Classification Name
AC-powered Ophthalmic Camera

Product Codes:
HKI

Device Classification
Class II
21 C.F.R. §886.1120

Predicate Device(s)
Next Sight Srl Nexy cleared in K180306

Device Description
The Resolve Fundus Camera is a fundus camera designed to perform fundus observation, automatic pupil tracking and focusing, automatic image capture, and image preservation. The Resolve Fundus Camera is used for non-mydriatic observation and capturing of retinal images. The fundus camera employes three internal imaging systems to operate: illumination system, imaging system and observation system. Auto-alignment and auto-focus algorithms are used to automatically find and capture desired images of the fundus.

The fundus camera features an internal, movable three-dimensional platform that allows for switching and precise positioning of the left and right eyes. The imaging process is done one eye at a time (left eye and then the right eye). The internal, moveable three-dimensional platform

contains two types of cameras: a set of infrared cameras (one on each side) as well as one main camera.

The observation system is used to detect and track the patient's pupil. Next, the illumination system determines the precise location of the ocular fundus after the pupil is located by the observation system. The system precisely finds the relationship between the position of the ocular fundus at different diopters, and the lens of the main camera.

Once the location of the fundus is found, a charge-coupled device (CCD) automatically captures a still image of the fundus through the main camera. The autofocus system utilizes a beam splitter to split a beam of light into two fine beams, which then image the ocular fundus onto the CCD. When the focus is at its sharpest position, the split beams align horizontally. At this point, the LED white light illumination system, installed in the imaging module on the three-dimensional movable platform, emits uniform white light of appropriate intensity to illuminate the ocular fundus. The imaging system captures the fundus information onto the CCD, and the received signals are displayed in real-time on a liquid crystal display (LCD) through the control system. Doctors can visually assess the patient's ocular fundus on the LCD screen.

Indications for Use
The Resolve Fundus Camera is an automatic eye-fundus camera intended for taking digital images of a human retina with or without the use of a mydriatic agent. It is intended for use as an aid to clinicians in the evaluation and diagnosis of ocular health.

Substantial Equivalence
Optain Health believes that the Resove Fundus Camera described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is a Class II medical device which is the Next Sight srl Nexy cleared in K180306. The intended use of the Resolve Fundus Camera is the same as the intended use of the predicate device which is to take digital images of the human retina. Both devices are prescription devices for use by trained healthcare providers. The Resolve Fundus Camera has the same technological characteristics as the predicate device. Both devices are fundus camera used for taking images of the retina. Both cameras are tabletop cameras with auto alignment and auto focus. Technical specifications of the two devices are similar and they comply with the relevant recognized consensus standards. Therefore, the Resolve Fundus Camera is substantially equivalent to the predicate device.

Resolve Fundus Camera Substantial Equivalence Table

Manufacturer	**Optain Health**	**Next Sight**	**Comparison**
Model	Resolve Fundus Camera	Nexy	-
510 (K) Number	K250683	K180306	-
Intended Use	To take digital images of the human retina	To take digital images of the human retina	Substantially equivalent
Indications for Use	The Resolve Fundus Camera is an automatic eye-fundus camera intended for taking digital images of a human retina	Nexy device is an automatic eye-fundus camera intended for taking digital images of a human	Substantially equivalent

Manufacturer	**Optain Health**	**Next Sight**	**Comparison**
Model	Resolve Fundus Camera	Nexy	-
	with or without the use of a mydriatic agent. It is intended for use as an aid to clinicians in evaluation and diagnosis of ocular health.	retina without the use of a mydriatic agent.	
Clearance Type	Prescription	Prescription	Substantially equivalent
Product Code	HKI	HKI	Substantially equivalent
Classification	II	II	Substantially equivalent
Device Type	Fundus non-mydriatic camera	Fundus non-mydriatic camera	Substantially equivalent
Form Factor	Tabletop camera	Tabletop camera	Substantially equivalent
User	Medical personnel	Medical personnel	Substantially equivalent
Alignment	Auto	Auto	Sustantially equivalent
Focusing	Auto	Auto	Substantially equivalent
Field of view	50 degrees	45 degrees	Substantially equivalent: the slightly larger field of view in the subject device does not impact substantial equivalence
Minimum pupil size	3.0 mm	3.8 mm	Substantially equivalent: the ability to take fundus images with a smaller pupil size does not impact substantial equivalence
Image sensor	CMOS	CMOS	Substantially equivalent
Sensor size	15 megapixel	2.1 megapixel	Substantially equivalent: the bigger sensor size does not impact substantial equivalence
Light source	LEDs	LEDs	Substantially equivalent: both light sources were tested ANSI Z80.36
Type of fixation light	White and continuous (during exam time)	Green and continuous (during exam time)	Substantially equivalent: both light sources were tested per ANSI Z80.36
Focus on retina-type of light	IR, LEDs and continuous source (during the focusing time)	IR, LEDs and continuous source (during the focusing time)	Substantially equivalent
Type of flash	Natural white LED	White LEDs in the visible range and pulsed (duration less than 50 ms) with annular shape on the cornea	Substantially equivalent
Exposure conditions	In accordance with flash duration time	In accordance with flash duration time	Substantially equivalent
Light feature	Polarized	Polarized	Substantially equivalent

Manufacturer	**Optain Health**	**Next Sight**	**Comparison**
Model	Resolve Fundus Camera	Nexy	-
Diopter adjustment	+20 D/-20 D	+15 D/-15 D	Substantiall equivalent
Fixation target	Internal OLED screen	Internal LEDs	Substantially equivalent: both light sources were tested per ANSI Z80.36
Display	5" full touch LCD mounted on camera unit	10.4" tablet separate from camera unit	Substantially equivalent: both devices have a screen that allows the user to interact with the camera
DICOM Compliant	Yes	Yes	Substantially equivalent
Data Connectivity	WiFi	WiFi and Bluetooth	Substantially equivalent
Power supply	Rechargeable lithium battery and AC/DC	AC/DC	Substantially equivalent
Standards Compliance			
Electrical safety	Per IEC 60601-1	Per IEC 60601-1	Substantially equivalent
EMC	Per IEC 60601-1-2	Per IEC 60601-1-2	Substantially equivalent
Biocompatibility	Per ISO 10993-1 for surface device, intact skin, limited duration	Per ISO 10993-1 for surface device, intact skin, limited duration	Substantially equivalent
Camera performance	ISO 10940 ISO 15004-2 ISO 15004-1	ISO 10940 ISO 15004-2 ISO 15004-1	Substantially equivalent

Performance Data

Non-clinical testing was performed to verify that the proposed device met all design specifications and is substantially equivalent to the predicate device.

- AAMI ANSI ES60601-1 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests
- IEC 60601-1-6 Medical electrical equipment-Part 1-6: General requirements for safety-Collateral Standard Usability
- ANSI Z80.36-2021 American National Standard for Ophthalmics-Light hazard protection for ophthalmic instruments
- ISO 10993-1: 2018 Biological evaluation of medical devices-Part 1: Evaluation and testing within risk management process
- ISO 10993-5: 2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2021 Biological evaluation of medical devices-Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices-Part 23: Tests for irritation
- ISO 10940 Second edition Ophthalmic instruments-Fundus cameras

- ISO 15004-1 Second edition Ophthalmic instruments-Fundamental requirements and test methods-Part 1: General requirements applicable to all ophthalmic instruments
- NEMA PS 3.1-3.20 2021e Digital and communications in medicine (DICOM) Set
- IEC 62133-2 Edition 1.0 2017 Secondary cells and batteries containing alkaline or other non-acid electrolysis-Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications-Part 2: Lithium systems.

Additionally, software verification and validation activities were performed to ensure the device performed as intended and software documentation appropriate for the Basic documentation set.

Conclusion

Performance testing shows that the Resolve™ Fundus Camera complies with relevant performance standards including electrical safety, electromagnetic compatibility, ocular light safety, and biocompatibility, and is substantially equivalent to the predicate device.