December 12, 2025

Remidio Innovative Solutions Private Limited
% Prithul Bom
Most responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K252120
Trade/Device Name: Fundus On Phone Non Mydriatic (FOP NM-10)
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: FUNDUS ON PHONE NON MYDRIATIC (FOP NM-10)
Dated: November 4, 2025
Received: November 4, 2025

Dear Prithul Bom:

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)*
K252120

Device Name
Fundus on Phone Non Mydriatic (FOP NM-10)

Indications for Use *(Describe)*
FOP NM-10 is an ophthalmic non-mydriatic digital camera using iPhone SE3 which captures images of the fundus of the human eye and surface as well as surrounding areas 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	Remidio Innovative Solutions Private Limited	
Address	No, 1-51-2/12, Vaccum Techniques Compound, Peenya 1st Stage, Peenya, Bengaluru, Karnataka, 560058, India	
Contact Person	Mr. Sundeep Agarwal	
Telephone	(+91) 9999095965	
Date Prepared	December 9th, 2025	
Subject Device	Trade Name	Fundus on Phone Non Mydriatic (FOP NM-10)
	510(k) number	K252120
	Common Name	Ophthalmic Camera
	Classification Name	Camera, Ophthalmic, AC powered (21 CFR 886.1120)
	Regulation Class	II
	Product Code	HKI
Predicate Devices	Primary Predicate Device:	
	Trade name:	Eyer Retinal Camera NM-STD
	510(k) number:	K221329
	Regulatory Class	II
	Product Code:	HKI
	Secondary Predicate Device:	
	Trade name:	Optomed Aurora Camera with Aurora Retinal Module and Aurora Anterior Module
	510(k) number:	K180378
	Regulatory Class	II
	Product Code:	HKI

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Description of the Device:

The FOP NM-10 is designed for imaging of the fundus and surface as well as surrounding area of the human eye, in a compact, portable format, with an inherent simplicity built in its operation and use. The application software (Remidio FOP) is loaded on top of the iOS operating system to enable the user to view, save, archive and retrieve the captured images of fundus and surface area of the human eye. It is a compact, battery-operated device that enables high-quality fundus photography without requiring pupil dilation. The device can be used in Hospitals and Ophthalmic clinics. The FOP NM-10 incorporates a 40° field of view (FOV) optical system optimized for high-resolution retinal imaging. The device employs infrared and white LED illumination to achieve adequate retinal illumination without causing discomfort to the patient. The device is built on a modular smartphone-based design, ensuring portability and ease of operation. The Remidio FOP app enables wireless control of illumination intensity, focus adjustments, capturing the images in Auto and manual modes, saving, editing and archiving images.

Physical Specifications

a) Field of View: 40° (for a minimum pupil size of 3mm)
b) Material: ABS, Silicone Rubber
c) Diopter Correction: -16D to +16D
d) Working Distance: 33mm

Output and Performance Characteristics

a) Illumination (Light Source): Infrared LED and Cool White LED
b) Camera Resolution: 64 line pairs per millimeter (lp/mm) (at the center)
c) ISO Range: ISO 200 and 400
d) Focus Adjustment: Manual and Tap to Focus
e) Internal Fixation: 8 fixation points
f) Operating temperature: 10° to 40°C
g) Relative Humidity: 10% to 85%
h) Atmospheric Pressure: 750 to 1060 hpa

Indications For Use

FOP NM-10 is an ophthalmic non-mydriatic digital camera using iPhone SE3 which captures images of the fundus of the human eye and surface as well as surrounding areas of the human eye.

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Comparison of Technological Characteristics

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.

S.No	Particulars	Subject Device	Predicate Device(s)	
			Primary Predicate Device	**Secondary Predicate Device**
1.	Name of the device	Fundus On Phone Non Mydriatic (FOP NM-10)	Eyer Retinal Camera NM-STD	Optomed Aurora Camera with Aurora Retinal Module and Aurora Anterior Module
2.	Applicant	Remidio Innovative Solutions Pvt Ltd Address: No, 1-51-2/12, Vacuum Techniques Compound,Peenya 1st Stage, Peenya, Bengaluru, Karnataka, 560058. INDIA	Phelcom Technologies Rua José Missali, 820 - Santa Felícia São Carlos, BR 13562-405	Optomed Oy Jyri Leskela Quality Manager Yrttipellontie 1 Oulu, 90230 Fi
3.	510(k) Number	K252120	K221329	K180378
4.	Classification Product code	HKI	HKI	HKI
5.	Regulation Name	Ophthalmic Camera	Ophthalmic Camera	Ophthalmic Camera
6.	Regulation Number	886.1120	886.1120	886.1120
7.	Class	Class II	Class II	Class II
8.	Indications for use	FOP NM-10 is an ophthalmic non-mydriatic digital camera using iPhone SE3 which captures images of the fundus of the human eye and surface as well as surrounding areas of the human eye.	Eyer® Retinal Camera model NMSTD is a medical non-mydriatic digital camera with a Samsung Galaxy S10 smartphone to capture digital images and videos of the fundus of the human eye, surface of the human eye and surrounding areas.	Optomed Aurora Camera is a medical digital camera that is used with dedicated optics modules intended to capture images and video of the fundus of the eye and surface of the eye. Optomed Aurora Camera with Optomed Aurora Retinal Module is intended to capture digital images and video of the

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				fundus of the human eye. Optomed Aurora Camera with Optomed Aurora Anterior Module is intended to capture digital images and video of the surface of the human eye and surrounding areas.
9.	Principle of Operation	The FOP NM-10 works in. **Non Mydriatic mode:** In this mode, IR LED is used for focusing the fundus & cool white LED is used as flash to capture the image of the fundus. The intensity levels have to be managed through a Software App using wireless technology (Bluetooth).	Eyer® uses near infrared illumination centered at 850 nm in the preview mode that allows retinal imaging without the use of eye drops for pupil dilation. The minimum pupil diameter to carry out retinal exams is 3 mm. In non-mydriatic imaging no mydriasis is needed because infrared light is used for targeting the fundus and white light is flashed when an image is taken	Optomed Aurora Camera is used with interchangeable optics modules Optomed Aurora Retinal Module and Optomed Aurora Anterior Module. Optics modules are attached to the camera with bayonet connectors. **Optomed Aurora Retinal Module** is intended for non-mydriatic fundus imaging. In non-mydriatic imaging no mydriasis is needed because infrared light is used for targeting the fundus and white light is flashed when an image is taken. **Optomed Aurora Anterior Module** is intended for imaging the surface of the eye and the surrounding areas. Optomed Aurora Anterior Module has two light sources for imaging: white and cobalt blue. Cobalt blue light enables capturing of fluorescent images. There are four focus windows to focus the image.
10.	Intended Patient Population	Images/ system is not patient population specific	Images/ system is not patient population specific	Images/ system is not patient Population specific
11.	Use	Intended to be used	Intended to be used	Intended to be used

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	Condition	without mydriasis	without mydriasis but can be used also with mydriatic drops.	without mydriasis but can be used also with mydriatic drops.
12.	Prescription Use only	Yes	Yes	Yes
13.	Where used (hospital, home, ambulance etc)	• Hospitals • Optical Shops • Ophthalmic Clinics	Hospitals, Clinics	Medical environment
14.	Use Environment	a) Operating Temperature: 10ºC to 40ºC b) Relative humidity: 10% to 85% c) Atmospheric Pressure: 750 hPa to 1060 hPa	a) Temperature: 5ºC (41ºF) to 40ºC (104ºF) b) Relative humidity: 5% to 75% c) Atmospheric pressure: 800 hPa to 1060 hPa	a) Temperature: -10 °C to +35 °C, b) Relative humidity: 10% to 80% c) Atmospheric pressure: 800 hPa to 1060 hPa
15.	Illumination Source	Infrared LED: o Wavelength: 855nm o Model: LZ1-00R602-0000 (OSRAM) Cool white LED: o Wavelength: 400 to 700 nm o Model: LZ1-00CW02-0065	White: OSRAM Oslon Compact; (LED) NIR: OSRAM CHIPLED; Target LEDs: Kingbright.	**Aurora Retinal Module:** White: OSRAM Oslon LUWH9GP; NIR: OSRAM Oslon SFH-4716 Target LEDs: Vishay VLMS1500-GS08. **Aurora Anterior Module**: White: OSRAM Advanced Power Topled LW G6SPEAFS-JKQL-1 Blue: OSRAM Advanced Power Topled LB G6SPV2BB-35-1
16.	Display System	IPS LCD, 4.0 inches, 44.1 cm2 (~60.8% screen-to-body ratio), Resolution 640 x 1136 pixels	5.8'', 1400x2960 pixels, Gorilla Glass protection (smartphone)	4.0'', TFT-LCD, 800x480 pixels, 16.7 M colors, anti-glare coating
17.	Camera Sensor Specification	Color CMOS camera minimum resolution 8 Mp to maximum resolution 12 Mp	Color CMOS camera maximum resolution 12 Mp	Color CMOS camera maximum resolution 5 Mp
18.	Diopter	From -16D to +16D	From -20 D to +20 D	From -20 D to +20 D

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	compensation			
19.	Field of View (FOV)	40º	45 degrees	50 x 40º
20.	Storage Media	Internal smartphone storage	Internal smartphone storage	Micro SDHC memory card
21.	Image Data Format	JPEG	JPEG	JPEG
22.	Weight	1.1kg	Smartphone Wt:157 g Device Weight: 700g	Aurora Camera: 514g, Aurora Retinal Module: 310g Aurora Anterior Module: 105g
23.	Battery	7.4V, 1500mAH Li-ion rechargeable battery	Rechargeable Li-Ion battery, 3.85 V, 3000 mAh (smartphone).	Rechargeable Li-Ion battery, 5000065, 3.63 V, 2600 mAH, 9.438 Wh.
24.	Connectivity/ Output terminals and data collection	Media transfer via Wi-Fi over HTTPS.	Media transfer via FTP, DICOM and CIFS communication.	USB(1.1) terminal (B-connector). Compatible with Windows® 7/8/10 And macOS(three latest versions).
25.	Min. diameter of pupil Required	3mm (without mydriatic drops).	The minimum pupil diameter to carry out retinal exams is 3 mm in (non-Mydriatic mode)	With small pupils it is recommended to use mydriatic drops.
26.	Photography mode	Color images, infrared and red free images.	Color retinography, red-free retinography and anterior segment imaging	Color image, Infrared (IR) image, red free and low red images
27.	Eye fixation lamp	Fixation target: Internal, 8 points	9 internal fixation dots to help the registration of macula and optic disc nerve centered and peripheral retinal images.	Optomed Aurora Retinal Module has 9 internal fixation targets for the patient to fixate on during imaging.
28.	External dimensions	(w x l x h): 93 x 284 x226 mm	Smartphone dimensions: 149.9 x 70.4 x 7.8mm Device dimensions (h x w x l): 185mmx85mmx160mm	Optics for retinal imaging: 69 (w) x 74 (h) x 160(d) mm; Camera dimensions: (122 (w)x 202(h) x 97(d) mm); Optics for anterior

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				imaging 71(w) x 80 (h)x 78 (d) mm
29.	Materials	Silicon Rubber for Eye Cup and Hand Gripper	Elastomeric material SILPURAN 2420 manufactured by (WACKER) and is a non-toxic silicone that has a certificate of conformity with ISO 10993 standard and USP Class IV Biological Tests.	Eyecup material: Retinal Module: Momentive LIM 6030AB. Anterior module: Momentive Silopren LSR 4040
30.	Performance Standards	1. IEC 60601-1:2005 + A1:2012 (Electrical Safety) 2. IEC 60601-1-2:2014 (EMC) 3. ISO 15004-1:2020, 4. ISO 15004-2:2024 (Ophthalmic Instruments) 5. ANSI Z80.36:2021 (Optical Performance) 6. ISO 10940:2009 (Fundus Cameras) 7. IEC 62366-1:2015 (Usability/Human Factors) 8. IEC 62304:2006+ AMD1:2015 (Software Verification & Validation) 9. ISO 10993-1 :2018, 10. ISO 10993-5:2009 11. ISO 10993-10: 2010 (Biocompatibility)	1. IEC 60601-1:2005 + A1:2012 + A2:2020 (edition 3.2) 2. (Electrical Safety) IEC 60601-1-2:2014 (edition 4.0); (EMC) 3. ISO 15004-1:2020 4. ANSI Z80.36:2016 5. ISO 10940:2009 6. NEMA PS3.1-30.20:2021 (DICOM Standards) 7. IEC 62304:2015 (Software Verification & Validation) 8. ISO 10993-1:2018 9. ISO 10993-5:2009 10. ISO 10993-10:2010 (Biocompatibility)	1. IEC 60601-1:2005 + A1:2012 (edition 3.1) (Electrical Safety) 2. IEC 60601-1-2:2014 (edition 4.0); (EMC) 3. ISO 15004-1:2006 4. ISO 15004-2:2007 5. IEC 62471: 2006 (Photobiological Safety) 6. ISO 10940:2009 7. IEC 62304:2006 + A1:2015 (Software Verification & Validation) 8. IEC 62366-1:2015 (Usability)

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Performance Data

The non-clinical testing conducted for FOP NM-10 to confirm the safety, effectiveness, and performance of the device are as follows:

Electrical Safety (ES) and Electromagnetic Compatibility (EMC):

FOP NM-10 was evaluated for electrical safety and electromagnetic compatibility in accordance with IEC 60601-1:2005 + A1:2012, ensuring compliance with general safety requirements for medical electrical equipment and IEC 60601-1-2:2014 – Verifying electromagnetic compatibility (EMC) to confirm that the device operates without interference in its intended environment.

Optical Safety:

The device was assessed for optical safety in accordance with ISO 15004-1:2021, ISO 15004-2:2024 and ANSI Z80.36:2021. These tests confirmed that FOP NM-10 meets the necessary optical safety criteria, ensuring patient safety during retinal imaging.

Optical Performance:

The device complies with the requirement of Standard ISO 10940:2009.

Software Verification and Validation:

FOP NM-10 underwent comprehensive software verification and validation per IEC 62304:2015 to ensure the fulfillment of the system requirements and functionality.

Biocompatibility:

FOP NM-10 includes an eyecup that comes into direct contact with the patient's skin around the eye and a hand gripper that is handled by the user during normal operation. The Eyecup and hand gripper have been tested as per ISO 10993-5 and ISO 10993-10 standards and are confirmed to be non-cytotoxic, non-irritating, and non-sensitizing to the skin.

Usability (Human Factors Engineering):

A usability evaluation was conducted in compliance with FDA Guidance: "Applying Human Factors and Usability Engineering to Medical Devices" (February 2016) – Ensuring the device is designed for safe and use. The evaluation confirmed that FOP NM-10 is user-friendly and suitable for its intended application, minimizing the risk of use errors. The usage of FOP NM-10 was evaluated to be suitable for its intended use and the device complies with the standards IEC 60601-1-6:2020.

Conclusion

In conclusion, we have demonstrated the substantial equivalence of FOP NM-10 with predicate devices. FOP NM-10 is safe and effective and no new issues or effectiveness are introduced by using this device. The basis for our conclusion is reached through successful review of product design specifications and testing results compared to the predicate devices.

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