January 16, 2026

Phelcom Technologies
José Roberto Santiciolli Filho
R&D Manager
Rua José Missali, 820, Pq Santa Felícia
São Carlos, São Paulo 13562-405
Brazil

Re: K251353
Trade/Device Name: Eyer 2
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: December 8, 2025
Received: December 8, 2025

Dear José Roberto Santiciolli Filho:

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,

BRADLEY S. CUNNINGHAM -S

CAPT Brad Cunningham, MSE, RAC
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251353

Device Name
Eyer 2

Indications for Use *(Describe)*
Eyer 2® is a portable fundus camera for use with the Samsung Galaxy S21, Galaxy S22, or Galaxy S23 smartphone to capture fundus images. It can be coupled to a front module for imaging of the surface of the eye and the surrounding areas, , including the meibomian glands.

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:	Phelcom Technologies S/A
Address:	820, José Missali St., Santa Felícia District. São Carlos - SP - Brazil. ZIP Code: 13562-405
Company phone:	+55 16 3413-3088
Contact person:	José Roberto Santiciolli Filho
Date:	January, 14, 2026

Subjective device:	Trade name:	**Eyer 2**
	510 (k) number:	**K251353**
	Common/usual name:	**Ophthalmic camera**
	Classification name:	**camera, ophthalmic, ac-powered (21 CFR 886.1120)**
	Regulatory Class:	**II**
	Product Code:	**HKI**
Predicate Device #1:	Trade name:	Eyer Retinal Camera NM-STD
	510 (k) number:	K221329
	Regulatory Class:	II
	Product Code:	HKI
Predicate Device #2:	Trade name:	Optomed Aurora Camera Optomed Aurora Retinal Module Optomed Aurora Anterior Module

	510 (k) number:	K180378
	Regulatory Class:	II
	Product Code:	HKI
Reference Device #1:	Trade name:	LipiView II Ocular Surface Interferometer
	510 (k) number:	K152869
	Regulatory Class:	II
	Product Code:	HKI

1. Description of the device

The **Eyer 2** is accompanied by accessories: frontal module for the ocular surface (1pc), dock station (charging station) (1pc), eye cap (1pc), lens protector (1 pc), storage case (1 pc), cleaning cloth (1 pc), allen wrench (1 pc), quick start guide (1 pc), welcome card (1 pc), shipping box (1 pc), power supply (1 pc), slit-lamp adapter (1 pc), sílica gel bags (2 pcs).

Eyer 2 is designed for use in a medical environment by healthcare professionals. Captured images and videos are used for documentation and consultation. The images and videos are securely stored in an internal smartphone application database.

For the retinal function, the **Eyer 2** is designed 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. The pupil does not respond to the infrared light so examination is convenient for the patient. With small pupils, it is recommended to use mydriatic drops. **Eyer 2** has fixation targets for the patient to fixate on during imaging. The middle fixation target provides a macula-center image. It is possible to fix the optical disc in the center by selecting the appropriate point.

For the ocular surface and surrounding areas function, **Eyer 2** has an ocular surface module with white, blue, and infrared light sources for imaging the eye surface and surrounding areas; in this configuration, the device does not make contact with the patient.

The transfer of images to a PC is carried out via DICOM, DICOMWEB, FTPS, or local folder connections, with the client responsible for the connection and subsequent storage.

The **Eyer 2** energy comes from the smartphone that has a rechargeable Li-Ion battery and is charged when the device is docked on the charge station, which is connected to the mains by a power supply cable.

2. Indications for Use

Eyer 2® is a portable fundus camera for use with the Samsung Galaxy S21, Galaxy S22, or Galaxy S23 smartphone to capture fundus images. It can be coupled to a front module for imaging of the surface of the eye and the surrounding areas, including the meibomian glands.

3. Contraindications

There are no known contraindications.

4. Comparison of Technological Characteristics

Table 4A below includes a summary of the technical information used in the substantial equivalence discussion.

4A- Comparison of Characteristics

Characteristic	Subject Device	Predicate Device #1	Predicate Device #2	Reference Device #1
Regulatory Information				
Device Name	**Eyer 2**	**Eyer Retinal Camera**	**Optomed Aurora Camera** **Optomed Aurora Retinal Module** **Optomed Aurora Anterior Module**	**LipiView II Ocular Surface Interferometer**
Manufacturer	Phelcom Technologies	Phelcom Technologies	Optomed	Tear Science
510(k) Number	K251353	K221329	K180378	K152869
Product Code	HKI	HKI	HKI	HKI
Device Class **CFR Section** **Common Name**	Class II 21 CFR 886.1120 Ophthalmic camera	Class II 21 CFR 886.1120 Ophthalmic camera	Class II 21 CFR 886.1120 Ophthalmic camera	Class II 21 CFR 886.1120 Ophthalmic camera and 21 CFR 886.1850 AC-powered slit lamp biomicroscope

Indications for Use	**Eyer 2®** is a portable fundus camera for use with the Samsung Galaxy S21, Galaxy S22, or Galaxy S23 smartphone to capture fundus images. It can be coupled to a front module for imaging of the surface of the eye and the surrounding areas, including the meibomian glands.	**Eyer Retinal Camera** is a medical 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 videos 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 surface of the human eye and surrounding areas. **Optomed Aurora Camera with Anterior Module** is intended to capture digital images and videos of the surface of the human eye and surrounding areas.	The **LipiView II Ocular Surface Interferometer** is an ophthalmic imaging device intended for use by a physician in adult patient to capture, archive, manipulate and store digital images of: ● Specular (interferometric) observations of the tear film. Using these images, LipiView® II measures the absolute thickness of the tear film lipid layer. ● Meibomian glands under near-infrared (NIR) illumination ● The ocular surface and eyelids under with illumination
Usage	Prescription use.	Prescription use.	Prescription use.	Prescription use.
Use Condition	Intended to be used without mydriasis but can be used also with mydriatic drops.	Intended to be used without mydriasis but can be used also with mydriatic drops.	Intended to be used without mydriasis but can be used also with mydriatic drops.	Intended to be used without mydriasis.
Target Population	The images/ system is not patient population specific.	The images/ system is not patient population specific.	The images/ system is not patient population specific.	Adult patients.

Hardware Design Features				
Illumination source	**Eyer 2** White: Lumileds L1RX-576000000000; NIR: OSRAM SFH 4053; Target: Display Winstar WEO006448AWPP3N00000 **Ocular Surface Module:** White: Lumileds L1RX-576000000000; NIR: Lumileds L1IZ-0940000000000; Blue: Lumileds LXz1-PB01	**Eyer Retinal Camera** White: OSRAM Oslon Compact, LUW CEUP.CE; NIR: OSRAM SFH 4053; Target LEDs: Kingbright, APG0603 SRC-TT	**Aurora Retinal Module:** White: OSRAM Oslon LUW-H9GP; NIR: OSRAM Oslon SFH-4716; Target LEDs: Vishay VLMS1500-GS08. **Aurora Anterior Module:** White: OSRAM Advanced Power Topled LW G6SP-EAFS-JKQL-1 Blue: OSRAM Advanced Power Topled LB G6SP-V2BB-35-1	**LipiView II Interferometer:** Visible White Class I LED illumination; Visible LED fixation light; Near-Infrared LEd illumination and transillumination of the eyelid.
Display system	6.2’’, 1080 x 2400 pixels, Gorilla Glass protection (Smartphone Samsung Galaxy S21); 6.1”, 1008x2340 pixels, Gorilla Glass protection (Smartphone Samsung Galaxy S22); 6.1”, 1008x2340 pixels, Gorilla Glass protection (Smartphone Samsung Galaxy S23).	6.1’’, 1400x3040 pixels, Gorilla Glass protection (Smartphone Samsung Galaxy S10).	4.0”, TFT-LCD, 800x480 pixels, 16.7 M colors, anti-glare coating.	Touchscreen display to view images;

Camera sensor specification	Color CMOS camera maximum resolution 12 Mp (Smartphone Samsung Galaxy S21). Color CMOS camera maximum resolution 50 Mp (Smartphone Samsung Galaxy S22). Color CMOS camera maximum resolution 50 Mp (Smartphone Samsung Galaxy S23).	Color CMOS camera maximum resolution 12 Mp (Smartphone Samsung Galaxy S10).	Color CMOS maximum resolution 5Mp.	Does not publicly disclose detailed technical specifications of camera sensors.
Diopter compensation	From -20D to +20D	From -20D to +20D.	From -20D to +20D.	-
Field of view	55x45 degrees	45 degrees.	50x40 degrees.	-
Storage media	Internal smartphone storage.	Internal smartphone storage.	MicroSDHC memory card.	Store images on computer and external media
Image data format	JPEG, MPEG-4.	JPEG, MPEG-4.	JPEG, MPEG-4.	JPEG, MPEG-4.
Weight	Eyer 2: 703 g Ocular Surface Front Module: 137 g	Eyer Retinal Camera: 700 g	Aurora Camera: 514 g; Aurora Retinal Module: 310 g; Aurora Anterior Module: 105 g.	5 - 10 kg.

Battery	Rechargeable Li-Ion battery, 3.85V, 4000 mAh (Smartphone Samsung Galaxy S21). Rechargeable Li-Ion battery, 3.85V, 3700 mAh (Smartphone Samsung Galaxy S22). Rechargeable Li-Ion battery, 3.85V, 3900 mAh (Smartphone Samsung Galaxy S23).	Rechargeable Li-Ion battery, 3.85V, 3400 mAh (Smartphone Samsung Galaxy S10).	Rechargeable Li-Ion battery, 5000065, 3.63V, 2600mAH.	AC- powered.
Output terminal and data collection	Media transfer via DICOM, DICOMWEB, FTPS or local folders connections	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).	Support for off-the-shelf USB printers and media that are compatible with Windows 7 and USB 2.0.
Standards	• IEC 60601-1:2005+A1:2012+A2:2020 (Edition 3.2); • IEC 60601-1-2:2014 (edition 4.0); • ISO 15004-1:2020; • ANSI Z80.36:2021; • ISO 10940:2009 • NEMA	• IEC 60601-1:2005+A1:2012+A2:2020 (Edition 3.2); • IEC 60601-1-2:2014 (edition 4.0); • ISO 15004-1:2020; • ANSI Z80.36:2016; • ISO 10940:2009 • NEMA PS3.1-30.20:2021;	• IEC 60601-1:2005+A1:2012+A2:2020 (Edition 3.2); • IEC 60601-1-2:2014 (edition 4.0); • IEC 60601-6:2010 + A1:2013 (edition 3.1); • IEC 62741:2006; • ISO 15004-1:2006; • ISO 15004-2:2007;	• IEC 60601-1:2005+A1:2012+A2:2020 (Edition 3.2); • IEC 60601-1-2:2017 (edition 3.0); • ISO 15004-1:2006; • ISO 15004-2:2007;

	PS3.1-30.20:2023e; • IEC 62304:2015; • ISO 10993-1:2018; • ISO 10993-5:2009; • ISO 10993-10:2010.	• IEC 62304:2015; • ISO 10993-1:2018; • ISO 10993-5:2009; • ISO 10993-10:2010.	• ISO 10940:2009; • ISO 10993-5:2009; • IEC 62304:2006+A1:2015; • IEC 62366-1:2015.	

5. Discussion of differences

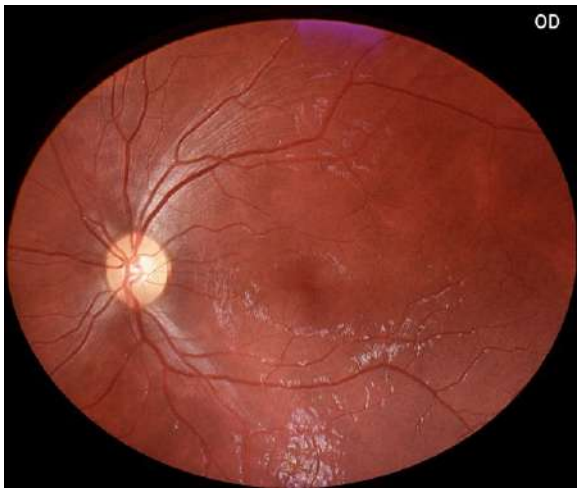
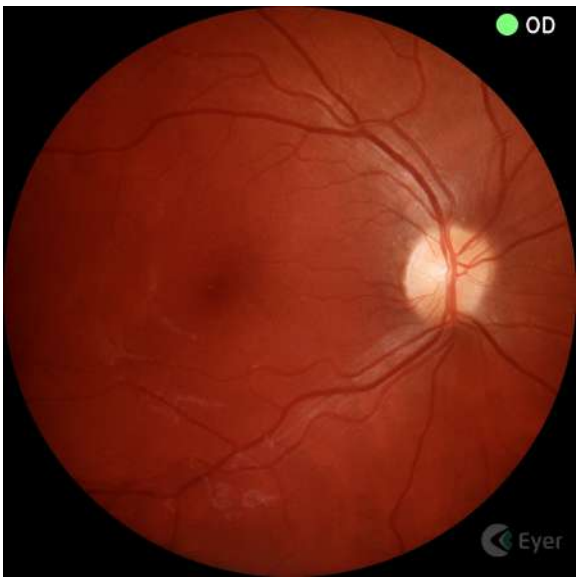
The Eyer 2 does have a significant difference between your predicates and reference device.

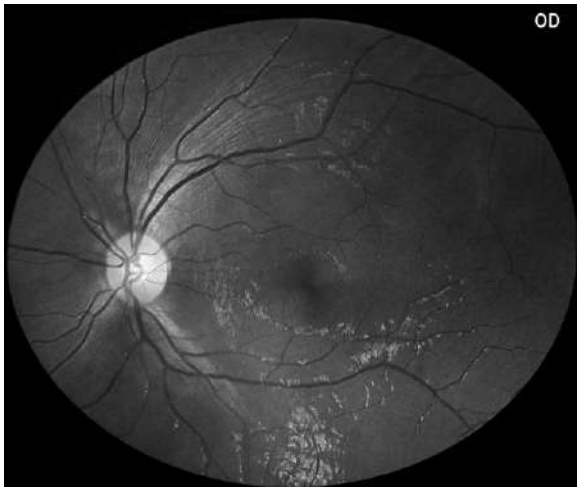
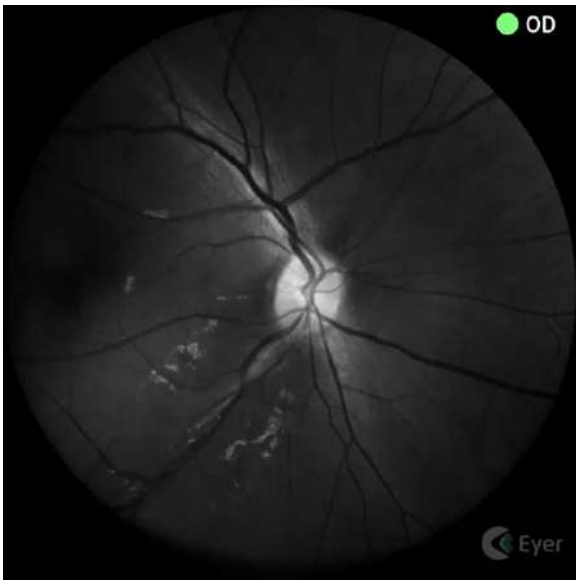
The following items are the differences between the devices:

- Exams

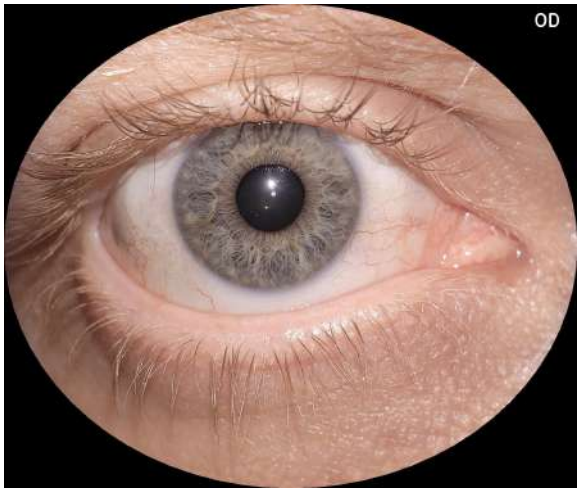
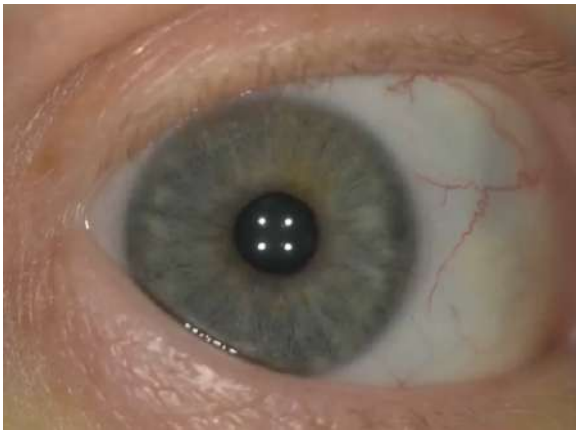
  The Eyer 2 combines most of the imaging functions present across all predicate and reference devices, offering color fundus photography, green channel fundus photography, infrared fundus photography, ocular surface imaging color and with blue excitation, and meibomian gland imaging under near-infrared illumination. One exception is the interferometry function of the LipiView II, which measures the lipid layer thickness of the tear film and is not included in the Eyer 2.

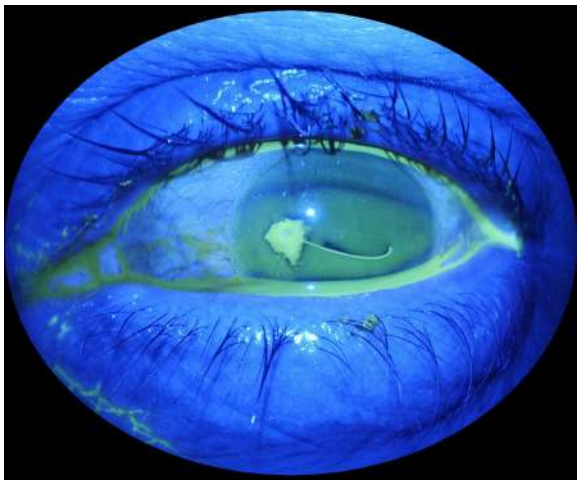
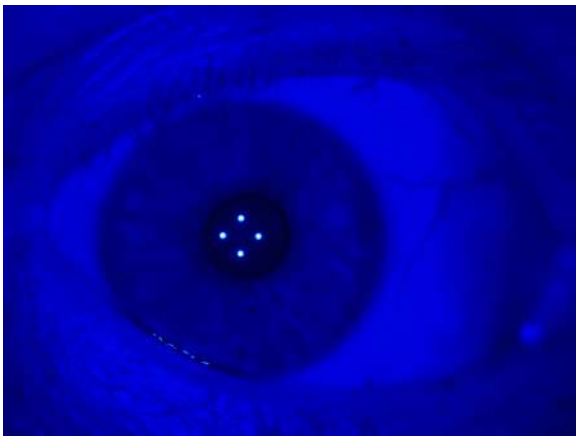
The Eyer 2 performs color fundus photography and is capable of generating digital green channel image, equivalent to those of the Eyer Retinal Camera, as shown in the images below:

	
Eyer 2 color exam	Eyer Retinal Camera color exam

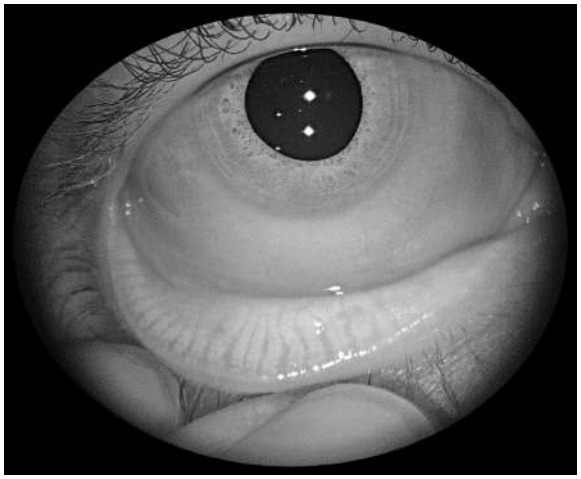
	
Eyer 2 digital green channel fundus	Eyer Retinal Camera green channel fundus

The Eyer 2 performs white and blue light examinations of the surface of the eye and the surrounding areas, equivalent to those of the Optomed Aurora Camera with Optomed Aurora Anterior Segment, as shown in the images below.

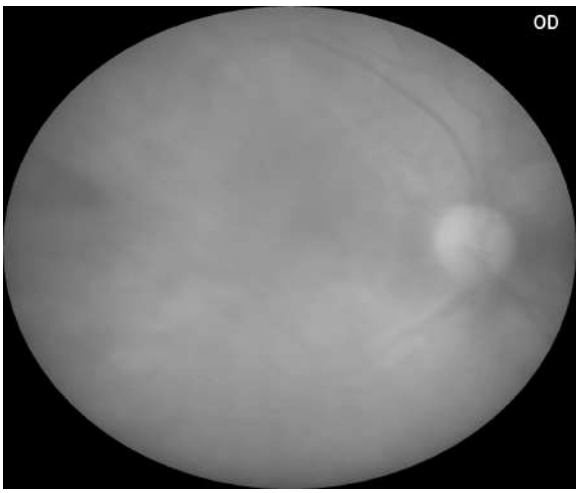
	
Eyer 2 with Ocular Surface Module with white excitation.	Optomed Aurora Camera with Optomed Aurora Anterior Module with white excitation.

	
Eyer 2 with Ocular Surface Module with blue excitation.	Optomed Aurora Camera with Optomed Aurora Anterior Module with blue excitation.

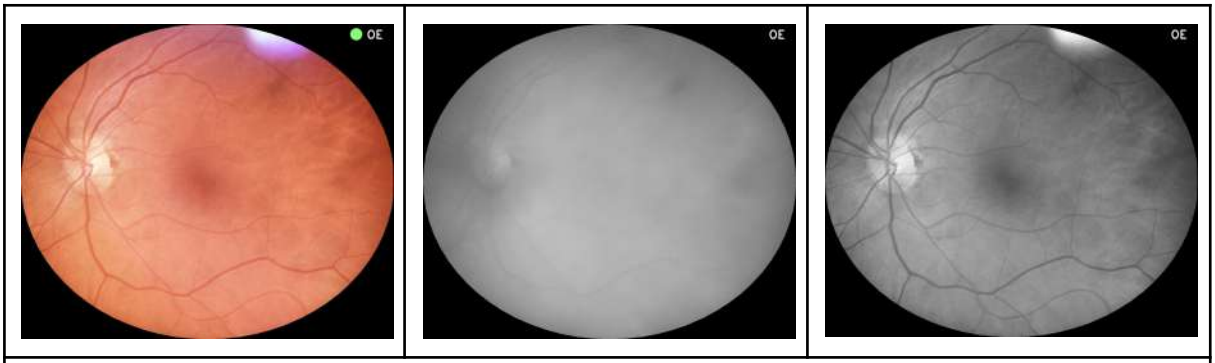
The meibography images obtained with the Eyer 2 are equivalent to those produced by the LipiView II Ocular Surface Interferometer, as shown in the images below:

	
Eyer 2 Ocular Surface with NIR excitation.	LipiView II meibography.

A difference between the subject device and the predicate and reference devices is that the **Eyer 2®** provides infrared fundus imaging. The infrared fundus image, together with the color fundus image and the green channel image, is automatically generated as part of the color fundus photography workflow, without requiring a separate imaging mode or additional user actions. The infrared fundus image is acquired immediately prior to the white-light exposure used for color fundus photography, being a frame saved from the image preview mode.



A typical result of an infrared fundus image acquired with the Eyer 2®



Set of images generated after image capture (color, infrared, and green channel)

- Display

  For the display system, Eyer 2 and Eyer Retinal Camera have similar image resolution, with the same amount of pixels on the screen. The Optomed Aurora Camera has a display with lower resolution. However, this does not interfere with the safety and effectiveness in relation to the predicates and reference device because all devices have the same final result, which is to capture images and videos from the fundus of the human eye, surface of the human eye and surrounding areas.

  The differences between the subject device and the predicate devices is that the Eyer 2 has better image resolution due to the amount of pixels on the screen, that is, the smartphone models used to capture images of the fundus of the eye.

- Data storage

Eyer 2 and Eyer Retinal Camera uses the internal memory of the smartphone whereas the Optomed Aurora Camera uses SD card.

- Battery

  The battery of the predicate Optomed Aurora Camera has 2600 mAh, the battery of the predicate Eyer Retinal camera has 3000 mAh, and the subject has 4000 mAh (for Samsung Galaxy S21 model), 3700 mAh (for Samsung Galaxy S22 model) and 3900 mAh (for Samsung Galaxy S23 model) which demonstrates that the subject device has a larger capacity of battery, which guarantees more autonomy. But this does not affect the effectiveness or safety of the device.

- Data collection

  Eyer 2 and Eyer Retinal Camera use Wifi whereas the Optomed Aurora Camera uses USB for data transmission.

- Field of view

  The field of view of the subject and predicate devices has a slight difference that is not significant for the intended use.

- Camera

  About the camera sensor specification, the subject device uses a camera with maximum resolution of 12 Mp, one of the predicates, the Eyer Retina Camera uses the same type of camera with maximum resolution of 12 Mp. The other predicate, the Optomed Aurora Camera uses a camera with maximum resolution of 5 Mp.

  Therefore, the subject device has a similar quality of image and resolution in relation to the Eyer Retinal Camera, and better quality and resolution in relation to the Optomed Aurora Camera, however it does not influence the indication for uses or affect the safety and effectiveness of the device.

6. Performance Data

The following performance data is provided in support of the substantial equivalence determination.

- **Electrical safety (ES) and electromagnetic compatibility (EMC)**

  Eyer 2 was tested according to all suitable clauses of IEC 60601-1:2005 + A1:2012 + A2:2020 (Edition 3.2) (Safety) and IEC 60601-1-2:2014 (Edition 4.0).

- **Optical Safety**

  Eyer 2 were tested according to the standard ANSI Z80.36:2021.

- **Optical Performance**

  Eyer 2 fulfills the requirements of standard ISO 10940:2009 - Ophthalmic instruments - Fundus Camera.

- **Software Verification and Validation**

  Software verification and validation were conducted to ensure the fulfillment of the system requirements and functionality. Eyer 2 complies with standard IEC 62304:2015, with Class A, no injury or damage to health is possible.

- **Environmental testing**

  Eyer 2 was tested according to ISO 15004-1:2020 and IEC 60601-1 standard to verify the mechanical stress and ambient conditions for use and storage as prescribed for the device. The devices fulfill the requirements of the standard.

- **Biocompatibility**

  Eyer 2 has an Eyecap that contacts skin around the eye during normal usage of the device. A piece made of an elastomeric material that touches the patient's skin during the exam is used to give firmness to the manipulation and create an environment isolated from external light.

  The chosen material was SILPURAN 2420 from manufacturer WACKER and is a non-toxic silicone that has a certificate of conformity with ISO 10993 standard and USP Class IV Biological Tests.

Conclusion

In conclusion, Phelcom Technologies believes that we have established the substantial equivalence of the subject Eyer 2 to the predicate and reference devices. No new issues of safety or effectiveness are introduced by using this device. The basis for our conclusion is reached through a successful review of product design specifications and testing results compared to the predicates and reference device.