February 22, 2023

Phelcom Technologies
Bruno Milhoci
Regulatory Affairs Coordinator
Passarini Regulatory Affairs of America LLC
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K221329
Trade/Device Name: Eyer Retinal Camera NM-STD
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: January 10, 2023
Received: January 23, 2023

Dear Bruno Milhoci:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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)*
K221329

Device Name
Eyer Retinal Camera model NM-STD

Indications for Use *(Describe)*
Eyer® Retinal Camera model NM-STD 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

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
Address:	Rua José Missali, 820 - Parque Santa Felícia Jardim - São Carlos - SP - CEP: 13562-405 - Brazil.
Company phone:	+55 (16) 3421 8488
Contact person:	Bruno Milhoci de Souza
Date:	February, 22, 2023

Subject device:	Trade name:	Eyer Retinal Camera NM-STD
	510(k) number:	K221329
	Common/ usual name:	Ophthalmic camera
	Classification name:	camera, ophthalmic, ac-powered (21 CFR 886.1120)
	Regulatory Class	II
	Product Code:	HKI
Predicate Device:	Trade name:	Optomed Aurora Camera Optomed Aurora Retinal Module Optomed Aurora Anterior Module
	510(k) number:	K180378
	Regulatory Class:	II
	Product code:	HKI

Description of the device

The Eyer Retinal Camera NM-STD retinography is accompanied by accessories: dock station (1pc), lens protector (1 pc), allen wrench (1pc), eyecap (2 pcs) cleaning cloth (1 pc) and slit lamp adapter (1pc).

Eyer Retinal Camera NM-STD is designed for use in a medical environment. Captured images and video are used for documentation and consultation. The images and videos are stored in an internal database of the smartphone application, in a security way.

For the retinal function, Eyer Retinal Camera NM-STD 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 Retinal Camera NM-STD has eleven 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 anterior function, Eyer Retinal Camera NM-STD has a white light source for imaging 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 FTP, DICOM or CFIS communication, with the client responsible for the connection and subsequent storage.

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

Indications for Use

Eyer® Retinal Camera model NM-STD 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

Contraindications:

There are no known contraindications.

Comparison of Technological Characteristics

Table 5-A bellow includes a summary of the technical information used in the substantial equivalence discussion.

5-A - Comparison of Characteristics

Characteristic	Predicate Device	Subject Device
Regulatory Information		
Device Name	Optomed Aurora Camera Optomed Aurora Retinal Module Optomed Aurora Anterior Module	Eyer Retinal Camera NM-STD
Manufacturer	Optomed Oy	Phelcom Technologies
510(k) Number	K180378	K221329
Product Code	HKI	HKI
Device Class CFR Section Common Name	Class II 21 CFR 886.1120 Ophthalmic camera	Class II 21 CFR 886.1120 Ophthalmic camera
Indications for Use	**Optomed Aurora Camera** is a medical digital camera that is used with dedicated optics modules intended to capture images and videos of fundus of the eye and surface of the eye. Optomed Aurora Camera with **Optomed Aurora Retinal Module** is intended to capture digital images and videos 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.	Eyer® Retinal Camera model NM-STD 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
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.
Target Population	Images/ system is not patient population specific.	Images/ system is not patient population specific.
Hardware Design Features		
Illumination source	**Aurora Retinal Module:**	**Eyer Retinal Camera:**

	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	White: OSRAM Oslon Compact; NIR: OSRAM CHIPLED; Target LEDs: Kingbright.
Display system	4.0'', TFT-LCD, 800x480 pixels, 16.7 M colors, anti-glare coating.	5.8'', 1400x2960 pixels, Gorilla Glass protection (smartphone)
Camera sensor specification	Color CMOS camera maximum resolution 5 Mp.	Color CMOS camera maximum resolution 12 Mp.
Diopter compensation	From -20 D to +20 D	From -20 D to +20 D
Field of view	50x40 degrees	45 degrees
Storage media	MicroSDHC memory card	Internal smartphone storage
Image data format	JPEG, MPEG-4	JPEG, MPEG-4
Weight	Aurora Camera: 514g Aurora Retinal Module: 310g Aurora Anterior Module: 105g	Eyer Retinal Camera: 700g
Battery	Rechargeable Li-Ion battery, 5000065, 3.63 V, 2600 mAH.	Rechargeable Li-Ion battery, 3.85 V , 3000 mAh (smartphone).
Output terminals and data collection	USB(1.1) terminal (B-connector). Compatible with Windows® 7/8/10 and macOS(three latest versions).	Media transfer via FTP, DICOM and CIFS communication.
Standard	○ IEC 60601-1:2005+A1:2012 (edition 3.1); ○ IEC 60601-1-2:2014 (edition 4.0); ○ IEC 60601-1-6:2010+A1:2013 (edition 3.1); ○ IEC 62471:2006 ○ ISO 15004-1:2006 ○ ISO 15004-2:2007 ○ ISO 10940:2009 ○ IEC 62304:2006+A1:2015 ○ IEC 62366-1:2015	○ 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 62304:2015 ○ ISO 10993-1:2018 ○ ISO 10993-5:2009 ○ ISO 10993-10:2010

Discussion of differences

The main difference between the Eyer Retinal Camera NM-STD and the Optomed Aurora is that in the Eyer the exam solutions are integrated into the equipment, while in Aurora solutions are modular.

The following items are differences between the devices:

- **Display**
  For the display system, the difference between the subject device and the predicate device is that the Eyer Retinal Camera has higher number of pixels on the screen. However, this does not interfere with the safety and effectiveness in relation to the predicate because both have the same result, which is to capture images and videos from the fundus of the human eye, surface of the human eye and surrounding areas.
- **Data storage**
  Eyer Retinal Camera NM-STD uses the internal memory of the smartphone whereas the predicate uses SD card.
- **Battery**
  The battery of the predicate has 2600 mAh, and the subject has 3000 mAh, but this does not affect the effectiveness or safety of the device.
- **Data collection**
  The main differences between the Eyer Retinal Camera NM-STD and Aurora Optomed are the type of transmission. The Eyer uses WiFi to transfer the data.
- **Field of View**
  The field of view of the subject device and of the predicate devices are similar.
- **Camera**
  About the camera sensor specification, the subject device uses a camera with the maximum resolution of 12Mp, and the predicate device uses a camera with maximum resolution of 5Mp, however it does not influence the indication for uses or affect the safety and effectiveness of the device.
- **Storage Media**
  The storage media of the smartphone on the subject device is internal and the predicate device has storage that is carried out on a memory card. And this does not have an impact on the effectiveness and safety of the device.

Performance Data

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

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

  Eyer Retinal Camera NM-STD was tested according to all suitable clauses of IEC 60601-1:2005+A1:2012+A2:2020 (edition 3.2) (safety) and #19-8 - IEC 60601-1-2:2014 (edition 4.0).

- **Optical Safety**

Eyer Retinal Camera NM-STD were tested according to the standard # 10-123 - ISO 15004-1 e #10-102 - ANSI Z80.36.

- **Optical Performance**

  Eyer Retinal Camera NM-STD fulfills the requirements of standard #10-74 - ISO 10940:2009 - Ophthalmic instruments - Fundus cameras.

- **Software Verification and Validation**

  Software verification and validation were conducted to ensure the fulfillment of the system requirements and functionality. Eyer Retinal Camera NM-STD complies with the standard #13-79 - IEC 62304:2015, with Class A.

- **Environmental testing**

  Eyer Retinal Camera NM-STD was tested according to # 10-123 - ISO 15004-1:2020 and IEC 60601-1 standards 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 Retinal Camera NM-STD have an eyecap that contacts skin around the eye during normal usage of the device. A piece made of elastomeric material that touches the patient's skin during the exam, 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.

- **Usability (Human Factors)**

  Eyer Retinal Camera NM-STD was designed and evaluated by following the principles depicted in the usability engineering process. The usage of Eyer Retinal Camera NM-STD was evaluated to be suitable for its intended use and the device complies with the standards IEC 60601-1-6:2013.

Conclusion

In conclusion, Phelcom Technologies believes that we have established substantial equivalence of the subject Eyer Retinal Camera NM-STD to the predicate. No new issues of safety 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 device.