September 6, 2023

NeoLight, LLC
Amy Oakes
Vice President of Quality & Regulatory Affairs
6630 Owens Drive
Pleasanton, California 94588

Re: K223575
Trade/Device Name: Pheonix ICON, Pheonix ICON GO
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: July 26, 2023
Received: July 27, 2023

Dear Amy Oakes:

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)*

K223575

Device Name
Phoenix ICON
Phoenix ICON GO

Indications for Use *(Describe)*

General ophthalmic imaging including retinal, corneal, and external structures of the 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

SECTION 5: 510(K) SUMMARY

As required by 21 CFR 807.92(c)

Submitter's Name and Address:
NeoLight, LLC
6630 Owen Dr
Pleasanton, CA 94588
USA

Contact Name and Information:
Amy Oakes
Vice President of Quality & Regulatory Affairs
Email: amy.oakes@theneolight.com
Phone: (480) 304-2165

Date Prepared:
November 23, 2022

Device Information:

Trade Name:	Phoenix ICON, Phoenix ICON GO
Device:	Camera, Ophthalmic, Ac-Powered
Review Panel:	Ophthalmic
Product Code:	HKI
Regulation Number:	886.1120
Regulatory Class:	2

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
K170527	Phoenix ICON	Phoenix Technology Group, LLC

Table 5.1: Predicate Device(s)

Manufacturer:
NeoLight, LLC
6630 Owen Dr
Pleasanton, CA 94588
USA

Device Description:
The Phoenix ICON system is an updated cart based retinal imaging system covering the design changes to date on the predicate device, Phoenix ICON. The Phoenix ICON GO retinal imaging system is a portable version of the predicate device, Phoenix ICON (K170527) including the design changes in the Phoenix ICON system.

Both the Phoenix ICON and Phoenix ICON GO are wide-field, handheld, high resolution, real-time retinal imaging devices. They are intended to be used for general ophthalmic imaging including retinal, corneal, and external structures of the eye. The intended users of the Phoenix ICON and Phoenix ICON GO are clinical imaging technicians, ophthalmic technicians, nurses, and physicians. The devices may be used in hospitals, medical clinics, and physician's offices.

The Phoenix ICON platform consists of either a cart based (Phoenix ICON) or portable (Phoenix ICON GO) control box used in conjunction with a hand-held camera (Handpiece) using interchangeable LED based light sources (White and Blue light). The Phoenix ICON cart contains an AC mains power attachment, a battery module, a keyboard interface, a monitor, and a computer with Phoenix ICON software. The Phoenix ICON GO contains a portable control box with battery function and has an interface for attachment to a specified laptop computer which runs the Phoenix ICON software. Both systems may be used with a Foot Pedal, White Light Module (standard), Blue Light Module (FA) and/or Diffuser accessory.

The Phoenix ICON Handpiece contains a wide-field, high resolution camera. The camera is used in three (3) modes, External Imaging (White Light), Retinal Imaging (White Light), and Fluorescein Angiography (Blue Light). For external imaging, the Diffuser accessory is placed over the lens tip to diffuse the light and provide for images of the outer surfaces of the eye. Both Retinal Imaging and Fluorescein Angiography are performed with the glass lens of the Handpiece coupled to the cornea via an imaging gel. In these imaging methods, LED light is emitted into the eye to illuminate the retina for image capture.

Both the Phoenix ICON and Phoenix ICON GO are software-controlled systems which can capture either video or still images and store them on the control box (Cart computer or GO laptop) for later review. The Phoenix ICON system may be connected to IT networks under IT supervision.

Indications for Use:
General ophthalmic imaging including retinal, corneal, and external structures of the eye.

Technological Characteristics:
The Phoenix ICON and Phoenix ICON GO function on the same technological characteristics as the predicate version of the Phoenix ICON. Electric powered (AC or battery) LED light (white or blue) is directed to the object to be imaged (retina or external eye features) and returned light is captured and saved as an image for review by a trained medical practitioner.

Table 5.2 below shows the comparison of characteristics between the Predicate and Subject Devices.

Characteristic	Predicate (K170527)	Subject Phoenix ICON	Subject Phoenix ICON Go	Comparison
Features	May be used with Fluorescein Angiography	Models sold with or without Fluorescein Angiography	Models sold with or without Fluorescein Angiography	Identical
Light Sources				
Source	LED	LED	LED	Identical
Wavelength	450-675 nm (white) 450-460 nm (blue)	450-675 nm (white) 450-460 nm (blue)	450-675 nm (white) 450-460 nm (blue)	Identical
Source Power	10 W	10 W	10 W	Identical
Maximum Intensity	19 mW/cm^2 (white) 20 mW/cm^2 (blue)	12 mW/cm^2 (white) 16 mW/cm^2 (blue)	12 mW/cm^2 (white) 16 mW/cm^2 (blue)	Reduced maximum output power does not negatively impact safety or efficacy
Intensity Adjustment	0-19 mW/cm^2 (white) 0-20 mW/cm^2 (blue)	0-12 mW/cm^2 (white) 0-16 mW/cm^2 (blue)	0-12 mW/cm^2 (white) 0-16 mW/cm^2 (blue)	Reduced maximum output power does not negatively impact safety or efficacy
Retinal Irradiance*	6.6 mW/cm^2 (white) 6.9 mW/cm^2 (blue)	Group 2 Instrument	Group 2 Instrument	Equivalent
External Fixation Light	None	None	None	Identical
Camera & Lensing				
CMOS Sensor	Sony IMX265, 1/1.8”	Sony IMX265LLR/LQR, 1/1.8”	Sony IMX265LLR/LQR, 1/1.8”	Similar
Field of View	100 degrees	100 degrees	100 degrees	Identical
Resolution	2048 x 1536 ppi	2048 x 1544 ppi	2048 x 1544 ppi	Similar
Frame Rate (video)	30 frames per second	30 frames per second	30 frames per second	Identical
Imaging Lens	Flat field external camera (white only)	Flat field external camera (white only)	Flat field external camera (white only)	Identical
Filters	500 & 515 nm edge blocking (blue only)	500 & 515 nm edge blocking (blue only)	500 & 515 nm edge blocking (blue only)	Identical
Data Capture	Still or Video Images	Still or Video Images	Still or Video Images	Identical
File Format	*.TIF *.JPEG *.AVI *.BMP	*.TIF *.JPEG *.AVI	*.TIF *.JPEG *.AVI	Removal of obsolete file type does not negatively impact safety or efficacy
Data Archive	Archive to Internal Database Or Export to external system via USB or local network connection	Archive to Internal Database Or Export to external system via USB or local network connection	Archive to Internal Database Or Export to external system via USB or local network connection	Identical
*Predicate Test Method ISO 15004:2-2007 / Subject Test Method ANSI Z80.36:2021				

Table 5.2: Specification Comparison to Predicate Device

Function and Safety Testing:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Phoenix ICON Go.

Characteristic	Standard(s) / Test Method	Results
Biocompatibility	ISO 10993-1 in conjunction with FDA Guidance Document "*Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*"	Pass
Cleaning Validation	>3 log reduction in active microbials	Pass
Electrical Safety	IEC 60601-1:2005+A1	Pass
	IEC 60601-1-6:2010 (3rd Ed) +A1:2013	Pass
	IEC/EN 60601-1-2:2014 (4th Ed)	Pass
	IEC 62366:2015	Pass
Visual & Dimensional	Visual and Dimensional inspection to internal specifications	Pass
Simulated Use	Image Clarity – Comparison between subject and predicate images to ensure equivalent visual quality of the captured images	Pass
Light Safety	ANSI Z80.36:2021	Pass
Packaging Validation	ASTM D4169-16	Pass

Table 5.3: Performance Testing

Conclusion:

NeoLight, LLC concludes that the Phoenix ICON and Phoenix ICON GO are substantially equivalent to the predicate device described herein.