DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

September 15, 2017

Phoenix Technology Group, Inc. Dba Phoenix Clinical
Christopher A. Henderson
Director of Regulatory Affairs and Quality Assurance
6630 Owens Drive
Pleasanton, CA 94588

Re: K170527
Trade/Device Name: Phoenix Clinical Icon
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: August 15, 2017
Received: August 16, 2017

Dear Christopher A. Henderson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bradley S. Cunningham -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170527

Device Name
Phoenix Clinical ICON

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 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92 510(k).

General Information

Applicant:	Phoenix Technology Group, Inc. 6630 Owens Drive Pleasanton, CA 94588
Contact Person	Christopher Henderson Director of QA and RA Phone: (925) 462-5000 x204 Facsimile: (925) 485-1155 E-Mail: chenderson@phoenixtechnologygroup.com
Date Prepared:	September 13, 2017
Trade Name(s):	Phoenix Clinical ICON, Phoenix ICON
Common Name:	Ophthalmic Imaging System, Retinal Camera, Fundus Camera
Classification:	II
Classification Name(s):	Ophthalmic Camera
Regulation Number:	886.1120
Product Code:	HKI
Classification Panel:	Ophthalmic
Predicate Device(s):	RetCam 3 K102859

Device Description:

The Phoenix Clinical ICON is a battery and AC-powered, cart-based, non-sterile, wide-field, handheld, high resolution, real-time retinal imaging device. It is intended to be used for general ophthalmic imaging including retinal, corneal, and external structures of the eye. The intended users of the Phoenix Clinical ICON are clinical imaging technicians, ophthalmic technicians, nurses, and physicians. The Phoenix Clinical ICON may be used in hospitals, medical clinics, and physician's offices. The Phoenix Clinical ICON is a system comprised of a hand-held camera with an interchangeable LED based light source incorporated into the hand piece that is attached to the cart. The cart contains the battery, the keyboard controls, monitor, attached foot pedal, and computer with software. The hand piece is designed such that the glass lens in the tip will come into contact with the cornea. LED light is emitted into the eye to illuminate the retina for image capture. The Phoenix ICON is operated by attaching the appropriate module (white or blue LED) to the handpiece and, after the software is running, placing the camera lens in direct contact with the patient's cornea. The Phoenix Clinical ICON software can capture either video or still images and store them on the cart computer for later review. The Phoenix Clinical ICON may be connected to, under IT supervision, IT networks.

Substantial Equivalence Summary of the ICON and the predicate device:
The design of the Phoenix ICON is substantially equivalent to the design of the predicate device. The methods of action and use are identical and the user functions (handpiece, software, procedure of image obtaining) are all identical in functionality between the ICON and the predicate. The intended use of both devices being "General Ophthalmic Imaging of retinal, corneal, and external structures" is identical. The proposed devices are substantially equivalent to the predicate devices in regards to its intended use, design, technology, and materials.

Discussion of key technological differences between the ICON and the predicate:

Device	K102859(Predicate)		K170527	
Features	White Light Module	FA Module	White Light Module	FA Module
Observation Light Source				
Light source type, wavelength	White light LED,	Blue light LED	10W White light LED, 450-675nm	10W Blue light LED, 450-460nm
Maximum Light source output power	21 mW/cm^2	85 mW/cm^2	6.1 mW/cm^2	28 mW/cm^2
Light intensity control	Zero to maximum	Zero to maximum	Zero to maximum	Zero to maximum
External fixation light (if any)	none	None	none	none
Camera				
Field of View	30 to 130 degrees	30 to 130 degrees	100 degrees	100 degrees
Resolution	Varies with lens between 13 microns and 47 microns	Varies with lens between 13 microns and 47 microns	Single lens at 12 microns	Single lens at 12 microns
Frame Rate	30 frames per second	30 frames per second	30 frames per second	30 frames per second
Other Accessories				
Insert filter	No insert filter needed.	Change light source at cart and remove objective lens and insert yellow barrier filter, filters >510nm	No insert filter needed.	Use blue LED module and flip filter on hand piece, barrier filter blocking band 500nm, edge wavelength 515nm
Imaging lens	Flat field inserted	N/A	Flat field external camera	N/A
Eye Contact Materials	Goniosol or GenTeal	Goniosol or GenTeal	Goniosol or GenTeal	Goniosol or GenTeal

Performance				
Imaging Format	.TIF/.JPEG/.AVI/.BMP	.TIF/.JPEG/.AVI/.BMP	.TIF/.JPEG/.AVI	.TIF/.JPEG/.AVI
Imaging Resolution	Varies with lens between 13 microns and 47 microns	Varies with lens between 13 microns and 47 microns	Single lens at 12 microns	Single lens at 12 microns

There are several key technological differences noted above in the Phoenix Clinical ICON system:

- Changes in light sources: Optical radiation hazard evaluation was performed that these changes will not affect the device safety.
- Changes in optical system, accessories and imaging: The image quality testing results were supportive of substantial equivalence to the predicate device.
- The predicate device has an LED source that is delivered to the hand piece that is generated on the cart where the application device has the LED source located in the hand piece that allows for the swapping of modules from white light to blue light for fluorescein angiography. This change has no affect in regards to safety or effectiveness and is merely a function of usability.

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

Bench Testing Summary:

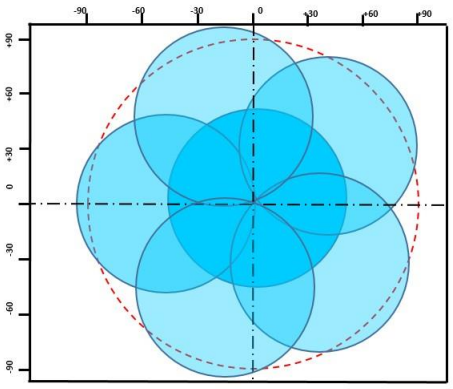
Testing per ISO 10940:2009:
ISO 10940:2009 - Ophthalmic instruments: fundus cameras was utilized as the first step for validation of substantial equivalence of image quality. The results were supportive of substantial equivalence to the predicate device.

Light safety testing per ISO 15004-2:
The Phoenix Clinical ICON was tested according to 15004-2:2007 to determine acceptable light safety limits for both the white and blue light. The test results demonstrate the ICON is in compliance with the of Group 2 instrument requirements provided by the standard.

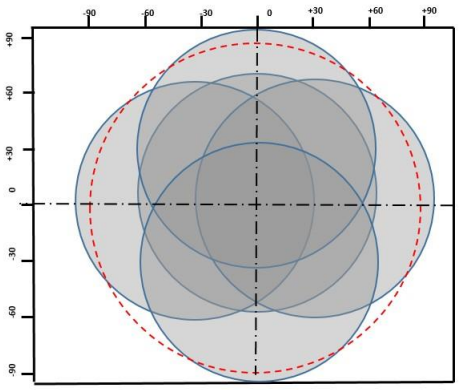
Retinal imaging testing compared to predicate device:
Using vascular edges as a resolution target and the NIH analytical tool ImageJ. The images from the predicate device and the ICON were presented to a panel of five clinicians for comparison in four parameters of image quality.

The entire retina can be imaged as a set of multiple images with both cameras. In the figure below it can be seen that the ICON can very adequately cover the retina with six images vs. five images from the RetCam.

ICON six images



RetCam 130 five images



Angle measured from the center of the eye

The resolution results were supportive of substantial equivalence to the predicate device.

Conclusion:

The bench performance tests and qualitative comparison of the retinal images support our conclusion of substantial equivalence of Phoenix Clinical ICON to the RetCam predicate.

Company Contact:

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