Chongqing Bio NewVision Medical Equipment Ltd.
℅ Ray Wang
Beijing Believe-Med Technology Service Co., Ltd.
R912, B#15, XiYueHui, No.5, YiHe North Rd.,
Fangshan District
Beijing, 102401 CHINA

Re: K190954
Trade/Device Name: Fundus Camera RetiCam 3100
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: December 13, 2019
Received: December 16, 2019

Dear Ray Wang:

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,

for Tieuvi Nguyen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known):* K190954

Device Name
Fundus Camera RetiCam 3100

Indications for Use *(Describe)*
The Fundus Camera RetiCam 3100 is intended to capture digital images of the posterior and external structures of the eye without the use of a mydriatic agent and is intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.

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.

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510(K) SUMMARY

This 510(k) Summary information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

APPLICANT INFORMATION

Date of Preparation: 01/20/2020

Sponsor Identification

Chongqing Bio NewVision Medical Equipment Ltd.
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IDENTIFICATION OF SUBJECT DEVICE

Trade Name: Fundus Camera RetiCam 3100

Regulation Number:21 CFR 886.1120

Regulation Name: camera, ophthalmic, ac-powered

Classification: II

Product Code: HKI

INDICATIONS FOR USE

The Fundus Camera RetiCam 3100 is intended to capture digital images of the posterior and external structures of the eye without the use of a mydriatic agent and is intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.

DEVICE DESCRIPTION

The RetiCam 3100 fundus camera is capable to capture, display, story, manage, process digital images of the posterior and external structures of the eye continuously, in real time.
The RetiCam 3100 fundus camera displays color fundus images continuously, in real time. The fundus

digital image acquisition and image processing system is capable to perform measurement of the length (digital caliper), and perform area measurements, image comparison and image montage.

The RetiCam 3100 fundus camera function module includes: optical module, mobile platform module, power supply module, control module, chin rest module.

Optical Module

The optical module is responsible for providing background light illumination, flash shooting, fixing lamp control, lens focal length adjustment and pupil monitoring of patients when the fundus camera works. The optical module mainly consists of two parts: the light source module and the lens light path module.

1) The light source component is the source of the light source when the product works, including background light, fixation light and flash when shooting.
2) The lens light path is responsible for reflecting the patient's fundus image to the digital camera. The functions of lens focusing, pupil size switching and double camera pupil monitoring are used to ensure that the patient's fundus image can be presented clearly and reliably.

Mobile Platform Module

This module is mainly responsible for control of the position of optical module (i.e. up, down, left, right, back and forth movement of the optical module). This includes X, Y, Z axes, which are designed with servo motor and bearing, which are controlled by PCB board in the control module.

Power Supply Module

Power supply to each module through medical switching power supply.

Control Module

To enable operators to control the product, understand the working status of the product, observe the patient's condition, and carry out the corresponding inspection work normally.
There is a computer system integrated in the product, the input and output function are realized by touch screen display.

Chin Rest Module

To place the patient's head and keep the patient's eyes stable and easy to observe.

IDENTIFICATION OF PREDICATE DEVICE(S)

Primary Predicate Device
510(k) Number: K122572
Product Name: iCam Fundus Camera
Manufacturer: Optovue, Inc.

Secondary Predicate Device
510(k) Number: K101935
Product Name: Digital Retinography System (DRS)
Manufacturer: CENTERVUE SPA

NON-CLINICAL TESTING

Non clinical tests were conducted to verify that the proposed device met all design specifications as designed Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- AAMI/ANSI/ES 60601-1:2005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical Electrical Equipment-Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And ISO 15004-1:2006 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments
- ISO 15004-2:2007 Ophthalmic instruments -- Fundamental requirements and test methods-- Part 2: Light hazard protection
- ISO 10940:2009 Ophthalmic instruments - Fundus cameras
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.
- ISO 10993-10:2010 Standard, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity
- ANSI Z80.36-2016 American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments

Summary of the results of performance testing and the device requirements based on ISO 10940

	Specification	Test Results	Testing Basis
Resolving Power (Field of view > 30°)	Centre 2: 60lp/mm	60 lp/mm	4.2 of ISO 10940
	Middle (r/2) 2: 40lp/mm	40 lp/mm	
	Periphery (r) 2: 25lp/mm	25 lp/mm	
Tolerance of angular field of view	50° ±5%	48.0°	
Tolerance of pixel pitch	6.45 um ±7%	6.59	
Range of Focus	-15D to +15D	Meet the specification	

CLINICAL TEST CONCLUSION

No clinical study is included in this submission.

SUBSTANTIALLY EQUIVALENT (SE) COMPARISON

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Primary Predicate Device (K122572)	Secondary Predicate Device (K101935)	Remark
Device name	Fundus Camera RetiCam 3100	iCam Fundus Camera	Digital Retinography System (DRS)	/
Classification Name	Ophthalmic Camera	Ophthalmic Camera	Ophthalmic Camera	SAME
Product Code	HKI	HKI	HKI	SAME
Regulation Number	886.1120	886.1120	886.1120	SAME
Comparison Statement	**The proposed device has same classification information as the predicate device.**			
Intended Use	The Fundus Camera RetiCam 3100 is intended to capture digital images of the posterior and external structures of the eye without the use of a mydriatic agent and is intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.	The iCam takes digital images of the posterior and external structures of the eye without the use of a mydriatic agent and is intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.	The CenterVue Digital Retinography System DRS is intended for taking digital images of a human retina without the use of a mydriatic agent.	SAME
Usage	Prescription Use	Prescription Use	Prescription Use	SAME
Comparison Statement	**The proposed device has similar intended use as the predicate device.**			
Main Unit Technical Specifications				
Operation Principle	The optical design of fundus camera is based on the principle of monocular indirect ophthalmoscopy. 1. Fundus observation A build in light ray from the infrared light LED source to illuminate the fundus. Alignment of the device is performed by build in eye tracking indicator and working distance indicator to adjust system to best XYZ position automatically.			SAME

	2. Image capture: System use split-image technique to do image focus adjustment automatically to capture the best quality of image. White light from LEDs Flash module irradiates the fundus. The light reflected from eye portions forms an image, and the image is captured by built-in color CMOS camera module for fundus image capture.			
Light Source	Observation: Infrared LED Image capture: White LED			SAME
Eye Fixation	Internal 9 points	Internal 6 points	Not Available	Analysis 1
Alignment	Manual focus tracking	Manual focus tracking	Automatic	SAME
Image Resolution	2304 x 1728 (4 MP)	1.3 MP	2592 x 1944 (5 MP)	Analysis 2
Field of view	50 degrees	45 degrees	45 degrees	Analysis 3
Operation Range	From -15 D to +15D	From -15 D to +15D	From -15 D to +15D	SAME
Interface	USB2.0, VGA, Network Port	USB 2.0	USB 2.0	Analysis 4
Minimum Pupil Size	3.0 mm	4.0 mm	4.0 mm	Analysis 5
Working Distance	35 mm	25 mm	37 mm	Analysis 6
Power Supplier	A.C. 100-240 V, 50/60 Hz, 220 VA	AC100V to 240V, 50/60Hz	100-240 VAC, 50/60 Hz	SAME
Comparison Statement:	**The proposed device has the similar main unit specifications with the predicate device. Please refer to the difference analysis below the table**			
Applied Standards:				
Biocompatibility	ISO10993-5&ISO10993-10	ISO10993-5&ISO10993-10	ISO10993-5&ISO10993-10	SAME
Electrical Safety	IEC60601-1	IEC60601-1	IEC60601-1	SAME
EMC	IEC60601-1-2	IEC60601-1-2	IEC60601-1-2	SAME
Performance	ISO 15004-1 ISO 15004-2 ISO 10940 ANSI Z80.36-2016	ISO 15004-1 ISO 15004-2 ISO 10940	ISO 15004-2 ISO 10940	SAME

Substantially Equivalent (SE) Conclusion

The subject device has differences with predicate device, the difference analysis shown as followings:

1. The eye fixation points are more than predicate device, it provides more different angle of fundus images.
2. The higher pixel provides high resolution image, it does not adversely affect safety and effectiveness.
3. The larger field view provides bigger observation range, it does not adversely affect safety and effectiveness.
4. More options are available for data transfer interface, all interface used are international standard interface, it does not adversely affect safety and effectiveness.
5. The smaller minimum pupil size could be applied to more wider patient population with same quality fundus images.
6. The working distance is changed by the different framework of device, it does not adversely affect safety and effectiveness.

Therefore, the above differences between the proposed device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. There is no new technology used in the subject device.

Conclusion: The proposed device is Substantially Equivalent (SE) in safety and effectiveness to the selected predicate devices