January 2, 2019

Crystalvue Medical Corporation
Oliver Lin
Director of Quality Assurance
No.116, Ln.956, Zhongshan Rd., Taoyuan Dist.,
Taoyuan, 33072 Tw

Re: K182199
Trade/Device Name: NFC-700 non-mydriatic auto fundus camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: September 21, 2018
Received: September 28, 2018

Dear Oliver Lin:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K182199

Device Name
NFC700 Non-Mydriatic Auto Fundus Camera

Indications for Use *(Describe)*
NFC-700 is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydriatic conditions.
NFC-700 is indicated for in-vivo viewing of the posterior and external area of the eye and the images are 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

Crystalvue Medical Corporation
NFC-700 Non-Mydriatic Auto Fundus Camera

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

Submitter

Company name:	Crystalvue Medical Corporation
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Contact Person:	Oliver Lin Director of Quality Assurance
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Date prepared:	08/10/2018

Device Information

Classification:	Class II
Trade Name:	NFC-700 Non-Mydriatic Auto Fundus Camera
Common Name:	Fundus Camera
Classification Name:	Ophthalmic Camera, AC power
Product Code:	HKI
Regulation Number:	21 CFR § 886.1120

Predicate Devices

Trade Name: Optovue iCam Fundus Camera
Classification Name: HKI, Ophthalmic Camera, AC power
510(k) Number: K122572

Intended Use

NFC-700 provides non-mydriatic, color posterior chamber and external images of the eye as an aid to clinicians in the evaluation and diagnosis of eye disease.

Indication for Use

NFC-700 is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydriatic conditions.

NFC-700 is indicated for in-vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.

Device Description

The NFC-700 is a non-contact fundus camera for capturing, storing and displaying the color fundus images with 12MP. It was designed a non-contact, high resolution digital imaging device, auto 3D tracking, fast and easy to use retinal imaging system and provide images of the eye as an aid to clinicians in the diagnosis of diabetic retinopathy, AMD, glaucoma and other retinal diseases.

NFC-700 was designed as an All-in-one system with full auto-focusing technique and easy operation. The large 10.1" touch screen makes it easy to control all of the operating procedures and makes the measurement and image check easily. NFC-700 uses NIR LED as illumination during alignment to the retina of patients' eyes, users can just touch the center of the pupil on the screen to capture the image. There also some interface located at the bottom of the device such as USB, HDMI, Ethernet make user to store, retrieve, archive and share the digital images by USB or LAN.

The dimensions of NFC-700 is about 485mm (L) x 282mm (W) x 500mm (H) and the whole weight should be not more than 17kg.

The detailed technological characteristics and specifications please refer to the paragraph of the substantial equivalence of this section.

Safety

All safety related parameters of NFC-700, such as light hazard protection, material biocompatibility, and IEC-60601 certification, has been tested and certified by recognized laboratories. The NFC-700 has the same indication and analysis features as predicate device; and all related test report of safety are show the NFC-700 is as safe as to the Optovue iCam Fundus Camera.

Biocompatibility Testing

The Biocompatibility test evaluation for NFC-700 was conducted in accordance with the ISO10993-1. The test result of biocompatibility test is complies the ISO 10993-1 standard.

Effectiveness

The validation of effectiveness of the NFC-700 has been analyzed in detail and the image quality is similar to the predicate device.

In clinical testing, the proportion of clinically useful images was tested by comparing the measured data to the reference device by physicians. The results provided that the NFC-700 is as effective as other devices which available on the market.

Substantial Equivalence

The NFC-700 is substantially equivalent to the predicate devices: Optovue iCam Fundus Camera (K122572).

After the detailed substantial equivalence comparison, besides the outer shape and the focus adjustment mode of NFC-700 are different from iCam Fundus Camera, the intended uses, technological, biological, and clinical performance of NFC-700 are equivalent with iCam Fundus Camera.

Product / Item	Crystalvue / NFC-700	Optovue / iCam Fundus Camera	Comparison Comments
510K number	K182199	K122572	--
Intended Use	NFC-700 provides non-mydriatic, color posterior chamber and external images of the eye as an aid to clinicians in the evaluation and diagnosis of eye disease.	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.	There is slight difference in the description of intended use, but the meaning is exactly the same with iCam Fundus Camera.
Indication for Use	NFC-700 is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina and external	The iCam 100 is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina and external	Both are almost the same. But we removed the part of content about what the device does not do (please see the

	areas of the eye to be evaluated under non-mydriatic conditions. NFC-700 is indicated for in-vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.	areas of the eye to be evaluated under non-mydriatic conditions. iCam 100 is indicated for in-vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health. iCam 100 provides images only and does not provide any diagnostic, pathological analysis or classification of ocular health or disease.	last paragraph of iCam IFU) to comply with 21 CFR 814.20 (3)(i).
Where Used	Hospital	Hospital	Exactly the same
Design			
-Shape	All in one	A camera head combine with a Base	NFC-700 is an All-In-One and fully auto alignment device. Based on the two reasons, the mechanical structure is different to iCam. It is reflects on the appearance of NFC-700. Furthermore, the main technological of NFC-700 is same as iCam. Thus, the differences won't make the safety problems but as effective as iCam.
-Dimensions(WxDxH)	282 x 485 x 492 (mm)	Head :150 x 225 x 335(mm) Base: 340 x 460 x 580 (mm)	
-Weight	17 Kg	Camera Head: 2 Kg Base: 10 Kg	
-Eye Fixation	Internal 10 points	Internal 6 point	The eye fixation point of NFC-700 is more than iCam, it provides more

			different angle of fundus images.
-Power Supply	AC100V to 240V, 50/60Hz (Auto selected)		Exactly the same
-Environment	Temp.:10-35˚C / Humidity:30-90%RH		Exactly the same
-Light source 1. Observation: 2. Flash:	1. Infrared LED 2. White LED		Exactly the same
-Type of Photography	Color / Digital red-free / Anterior eye image		Exactly the same
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. **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.		The NFC-700 and iCam fundus camera have exactly same technology principle.
Material of Chinrest	ABS	ABS	Exactly the same
Material of Forehead Rest	TPE	FEP	The biocompatibility has been certified by recognized lab, thus the different material do not affect the safety.
Safety	IEC60601-1 compliance IEC 60601-1-2 compliance	IEC60601-1 compliance IEC 60601-1-2 compliance	Exactly the same
Performance			
-Image (resolution)	12 MP	1.3 MP	The higher pixel only provides high resolution image, it

			does not adversely affect safety and effectiveness.
-Alignment	Fully automatic 3D tracking	Manual focus tracking	For the different of alignment method, We analyzed the possible hazards and then set the security measures on the appearance design of camera head and the distance of camera-to-patient. Thus, the difference does not adversely affect safety and effectiveness.
-Field of View	45°	45°	Exactly the same
-Minimum Pupil Size	4.0 mm	4.0 mm	Exactly the same
-Working Distance	25 mm	25 mm	Exactly the same
-Operation Range (Focus Adjustment Range): 1. Without compensation lens: 2. With compensation lens:	-15 to +10 D -30D to -10D or +5D to +30D	-15 to +10 D -35D to -10D or +5D to +30D	Similarity- In the performance test of the NFC-700, we used the same focus adjustment range as iCam to test and it's also passed. The focus range of NFC-700 is within the test range. Thus, the difference does not adversely affect safety and effectiveness.
Interface	USB2.0 / Ethernet / HDMI	USB 2.0	The interface is more diversified provides user more easy and convenient image transfer method.

Performance Data

(a) Software Validation

The Software verification and validation testing were conducted and documentation was provided as recommended by IEC-62304 "Medical Device Software – Software Life Cycle Processes". The software of NFC-700 is classified as Class A according to the classification criterion of IEC 62304:2015, and also as Minor Level of Concern in accordance with U.S. FDA Guidance since the failure usually will not cause the patient injury. Application of risk management to medical devices to show the software used in the NFC-700 is conform the safety principles.

(b) Bench Testing

The NFC-700 has undergone performance testing before release to ensure that the device and its software meet the functional requirements and to demonstrate equivalence to the predicated devices.

A summary of the results of performance testing and the device requirements follows:

Performance Item	Requirements	Test Result
Resolving power	≧60 line pairs/mm at the center of the field ≧40 line pairs/mm at the mid field (r/2) ≧25 line pairs/mm at the periphery of the field (r)	Pass Pass Pass
Field of view	45 degrees	Pass
Pixel pitch	5.12 μm	Pass
Alignment illumination	The alignment illumination intensity by NIR-LED should be able to adjust output level by SW control.	Pass
Flash illumination	The flash illumination intensity by White LED should be able to adjust output level by SW control.	Pass
Range of focus	-15 to +10 D (Without compensation lens) -35D to -10D or +5D to +30D (With compensation lens)	Pass Pass
Minimum pupil size	4.0 mm	Pass
Working distance	25 mm	Pass
Alignment	With fully automatic 3D tracking. The average test	Pass

	time should≦30 seconds.	
Image quality	The quality of Fundus images captured by NFC-700 should be same as predicate device on same people.	Pass

(c) Clinical Testing

This is a single-site study evaluating the non-inferiority of the auto-focus study device, NFC-700, relative to the predicate with regards to image quality. Consented subjects will undergo ophthalmic examination and a series of fundus photos on the study eye with the NFC-700 and the predicate device.

The clinical testing of NFC-700 was study the 119 patient. Photos will be based upon image quality assessment for identification of clinically significant features using a 5-point grading scale.

(1). Significant clinical manifestation zone:

Among the 119 subjects, their fundus images taken by the NFC-700 can mostly and clearly demonstrate significant clinical manifestation zones such as the optic disc, macula and retinal vessels.

Whether the image can clearly demonstrate the following significant clinical manifestations for interpretation?	Yes	No
(a) Optic disc	118	1
(b) Macula	118	1
(c) Retinal vessels	117	2

(2). Image quality factors:

The ophthalmologist reviews all fundus images from the 119 subjects taken by the NFC-700 one-by-one. Most image quality is evaluated as good.

Whether the image can clearly demonstrate the following significant clinical manifestations for interpretation?	Yes	No
(a). Good focus	116	3
(b). Appropriate brightness	107	12
(c). Good view field identification	110	9
(d). No image defects	109	10
(e). No small pupil interference	119	0
(f). No ocular media opacity	111	8

(3). Results interpretation:

This study total examined 119 eyes, of which the fundus images were taken both by

the investigational camera (NFC-700) and the reference camera (FundusVue). The grading results are summarized in the following table:

Grading Statistics	FundusVue (reference camera)						
NFC-700 (investigational camera)	**Grading**	**1**	**2**	**3**	**4**	**5**	**Total**
	1	0	0	0	0	0	0
	2	0	3	0	0	0	3
	3	0	1	1	0	0	2
	4	0	0	0	15	10	25
	5	0	0	0	11	78	89
	Total	0	4	1	26	88	119

According to the preliminary statistics (the primary endpoints based on the dichotomy) listed in the above table, the ratio of images with "sufficient for clinical interpretation" (3~5 points) quality taken by the investigational device (NFC-700) vs. by the reference device (FundusVue) is 97.5% and 96.6%, respectively; which proven that the performance of NFC-700 is equivalent to the listed medical device FundusVue.

Conclusion

As described in this 510(k) Summary, comprehensive testing and analysis was conducted on the NFC-700 to ensure that the device is safe and effective for its intended use when used in accordance with its instructions for use. The Performance Data demonstrate that NFC-700 is as safe and effective as predicate device, Optovue iCam Fundus Camera. Based on the information in this submission, the NFC-700 has the same intended use, technological characteristics, and operation principles as its predicate devices. Therefore, NFC-700 is substantially equivalent to the predicate device.