April 13, 2020

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

Re: K210197
Trade/Device Name: NFC-600 Automated Portable Retinal Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: March 18, 2021
Received: March 23, 2021

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/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)*
K210197

Device Name
NFC-600 Automated Portable Retinal Camera

Indications for Use *(Describe)*
NFC-600 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-600 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.

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510(k) Summary

Crystalvue Medical Corporation

NFC-600 Automated Portable Retinal 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

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Date prepared:	February 19, 2021

Device Information

Classification:	Class II
Trade Name:	NFC-600 Automated Portable Retinal Camera
Common Name:	Fundus Camera
Classification Name:	Ophthalmic Camera, AC power
Product Code:	HKI
Regulation Number:	21 CFR § 886.1120

Predicate Devices

Trade Name: NFC-700 Non-Mydriatic Auto Fundus Camera (Crystalvue Medical Corp.)
Classification Name: HKI, Ophthalmic Camera, AC power
510(k) Number: K182199

Intended Use

NFC-600 provides non-mydriatic color retina and external images of the eye as an aid to clinicians in the evaluation and diagnosis of eye disease.

Indication for Use

NFC-600 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-600 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

NFC-600 is a non-contact fundus camera for capturing, storing and displaying the color fundus images with 12 million pixels. It was designed a non-contact, images provide high resolution digital imaging device, auto 3D tracking, auto exposure, and auto capture functions, a portable device with auto-focusing technique and easy operation.
Different from the all-in-one design (built-in PC module) of previous cleared product, NFC-600 removed the embedded computer module and designed to use the USB 2.0 port which is located behind the base to connect to the user's PC or laptop, making the device smaller and lighter to achieve a portable design. The dimensions of NFC-600 is about 330mm (L)x 260mm (W)x 330mm (H) and the whole weight not more than 12 kg.
Same as the predicate device, NFC-600 uses NIR LED as illumination during alignment to the retina of patients' eyes. All operations are performed through the proprietary software, which will be installed in the user's PC or laptop to capture, store, view, retrieve, and export ophthalmic images.

Purpose of the Special 510(k)

The purpose for this 510(k) notification is to modify the current legally marketed device of Crystalvue Medical Corporation: NFC-700 Non-mydriatic Auto Fundus Camera (K182199). The modified device is referred to as NFC-600 Automated Portable Retinal Camera.

Summary of Modification

The difference between subject device and predicate device is that NFC-600 removed the embedded computer module from the device and changes it to an external PC or laptop, thereby making the appearance of NFC-600 smaller and lighter. In order to remove the embedded computer module from the device, the control circuit and PCB outline of control board need to do design modification to be used in NFC-600.

Performance Data

As describe in Summary of Modification paragraph, in order to evaluate whether the changed control circuit and PCB control board of NFC-600 affect the safety and effectiveness, non-clinical tests including electrical safety and electromagnetic compatibility were conducted. It has been tested and found to comply with the consensus standards IEC 60601-1:2005 (MOD) and IEC 60601-1-2:2014.

The optical design of NFC-600 is exactly the same as the predicate device. It had been tested and complies with the following FDA- recognized consensus standards: ISO 15004-1:2006, ANSI Z80.36:2016 and ISO 10940:2009.

The materials of contact parts with patients in the NFC-600 are the same as predicate device and had been evaluated according to ISO10993 series; the software used in the NFC-600 is identical to the predicate device, and it was validated according to the standard IEC 62304:2015.

Above tests all meet the requirement and without any deviation, the modified NFC-600 as intended and produced the expected results, demonstrating that the safety and effectiveness of the modified device is as same as the predicate.

Substantial Equivalence

The subject device **NFC-600 Automated Portable Retinal Camera** has the following similarities to the predicate NFC-700 Auto Non-Mydriatic Fundus Camera cleared under 510(k) K182199:

- Have the same intended use / indications for use
- Uses the same operating principle
- With the same basic technological characteristics and performance
- With the same materials

The modification was evaluated by Crystalvue to determine if they could affect the safety or effectiveness of the subject device and it was determined that it does not raise any new questions of safety and effectiveness. Verification and validation was performed to ensure that the device performs as intended.
In summary, we believe the NFC-600 is substantially equivalent to predicate device NFC-700.
A table comparing the technological characteristics with the predicate device is provided below.

Comparison of Technological Characteristics with the Predicate Device

Item \ Product	Subject Device NFC-600	Predicate Device (K182199)	Comparison
Intended Use	NFC-600 provides non-mydriatic color retina and external images of the eye as an aid to clinicians in the evaluation and diagnosis of eye disease.	NFC-700 provides non-mydriatic color retina and external images of the eye as an aid to clinicians in the evaluation and diagnosis of eye disease.	No changes
Indication for Use	NFC-600 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-600 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.	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.	No changes
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.		No changes.

Appearance			
-Shape	External PC or laptop	All in one (embedded PC)	NFC-700 is an All-In-One device; NFC-600 adopts external PC or laptop, making NFC-600 smaller and lighter.
-Dimensions (mm)	W260 x D330 x H330	W282 x D485 x H492	
-Weight	12 Kg	17 Kg	
Technological Characteristics			
-Image (resolution)	12 MP		No changes.
-Eye Fixation	Internal 10 points		No changes.
-Light source	Observation: NIR LED / Flash: White LED		No changes.
-Alignment	Fully automatic 3D tracking		No changes.
Materials			
-Chinrest	ABS		No changes.
-Forehead rest	TPE		No changes.
Performance			
-Field of View	45°		No changes.
-Minimum Pupil Size	4.0 mm		No changes.
-Working Distance	25 mm		No changes.
-Focus Adjustment Range	1.Without compensation lens: -15 to +10 D 2.With compensation lens: -30D to -10D or +5D to +30D		No changes.

Conclusion

Based on the performance data, identical intended use and technological characteristics and the similarities in functional design, the subject device NFC-600 is substantially equivalent to the NFC-700 (K182199) and the modification does not raise any new questions regarding safety and effectiveness. Performance and safety data demonstrate that the modified device is as safe and effective as the predicate device.