July 23, 2020

Canon Inc.
Akira Hirai
General Manager
9-1, Imaikami-cho
Nakahara-ku, Kawasaki, Kanagawa 211-8501
Japan

Re: K201122
Trade/Device Name: Canon non-mydriatic retinal camera CR series (Model CR-2 AF and CR-2 Plus AF)
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: June 18, 2020
Received: June 22, 2020

Dear Akira Hirai:

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 Ng
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number

K201122

Device Name

Canon non-mydriatic retinal camera CR series (Model CR-2 AF and CR-2 Plus AF)

Indications for Use *(Describe)*

Canon non-mydriatic retinal camera CR series (CR-2 plus AF and CR-2 AF) is intended to be used for taking digital images of the retina of the human eye without mydriatic. The CR-2 plus AF has the following photography modes: color, red-free, cobalt digital and fundus autofluorescence (FAF). The CR-2 AF has the following photography modes: color, red-free, cobalt digital and additional infrared photography for anterior segment.

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

Submitter
Canon Inc.
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Contact person
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Date prepared
July 21, 2020

Submission type
Special 510(k)

Name of Device

Trade/Device Name:	Canon non-mydriatic retinal camera CR series (Model CR-2 AF and CR-2 Plus AF)
Regulation Number:	21 CFR 886.1120
Regulation Name:	Ophthalmic Camera
Regulatory Class:	Class II
Product Code:	HKI

Predicate Device
K123208

Trade/Device Name:	Digital Retinal Camera CR-2 Plus AF
Regulation Number:	21 CFR 886.1120
Regulation Name:	Ophthalmic Camera
Regulatory Class:	Class II
Product Code:	HKI

Device Description

The Canon non-mydriatic retinal camera CR series is composed of two retinal cameras and its control software and is used for taking digital images of a human retina without mydriatic.

Two retinal cameras: The CR-2 Plus AF and CR-2 AF

- Both models take digital photographic retinal images of patient's eyes across an angle of view of 45 degrees, and have autofocus and automatic shooting of retinal image, and automatic switching from anterior segment image to retinal image.

- The CR-2 Plus AF camera is identical to the camera cleared under K123208. The photography mode includes color, red-free, cobalt and fundus autofluorescence (FAF).

- The CR-2 AF camera is modified version of the predicate CR-2 Plus AF (K123208). Most of the specifications are identical to the predicate; however, the photography mode does not include fundus autofluorescence (FAF) photography.

- Both the CR-2 AF and the CR-2 Plus AF uses infrared light to observe the anterior segment, but CR-2 AF can save such an image.

Two Software: Retinal image control software (RICS) and Non-myd RC Capture Utility software (CU) programs

- RICS software program supports browsing, processing, and storage function of the images. It also supports the output of the images to the DICOM storage server, export in DICOM or JPEG format and output to a printer.

- CU software program is a simplified version of RICS, without most of the graphic user interface and the database. It allows user to capture and transfer the retinal images from the retinal camera to the PC.

Both RICS and CU software programs are compatible with both CR-2 AF and CR-2 Plus AF cameras.

Indications for Use

> Canon non-mydriatic retinal camera CR series (CR-2 plus AF and CR-2 AF) is intended to be used for taking digital images of the retina of the human eye without mydriatic. The CR-2 plus AF has the following photography modes: color, red-free, cobalt digital and fundus autofluorescence (FAF). The CR-2 AF has the following photography modes: color, red-free, cobalt digital and additional infrared photography for anterior segment.

The Indication for Use for predicate device, Digital Retinal Camera CR-2 Plus AF is the follows:

> "The Digital Retinal Camera CR-2 Plus AF is intended to be used for taking digital images of the retina of the human eye without a mydriatic. The CR-2 Plus AF has the following photography modes: color, red free, cobalt digital and fundus autofluorescence (FAF)."

It appears the intended for use of Canon non-mydriatic retinal camera CR series and predicate device is identical.

Discussion of Substantial Equivalence

The CR-2 AF is modified from the predicate CR-2 Plus AF (K123208) and most of the specifications are identical to the predicate CR-2 Plus AF, the major differences are in the following aspects:

- The photography mode: The CR-2 AF has the following photography modes: color, red-free, cobalt and infrared photography for anterior segment. The CR-2 AF doesn't have the fundus autofluorescence photography (FAF) mode while the CR-2 Plus AF (K123208) has.

- The light source: The CR-2 Plus AF (K123208) needs to equip a large power supply box, capacitor and Xenon tube for the FAF photography because the FAF photography needs high light intensity for photographing images but the CR-2 AF doesn't have FAF photography feature and therefore the CR-2 AF adopts a White LED as a light source, whose output is lower than that of Xenon tube.

  It is verified that there is no new risk associated with the light source change. The light hazard protection evaluation of CR-2 AF was evaluated to meet the eye safety limits of the Group 1 instrument based on ANSI Z80.36:2016 - Ophthalmics - Light Hazard Protection for Ophthalmic Instruments.

- The graphic user interface: Software CU is derived from the RICS by modifying the graphic user interface and removing the database from the RICS. CU can save the retinal images to the designated folder to transfer the images to the 3rd party software.

Therefore, the above differences between the proposed device and predicate device do not affect the basic design principle, usage, effectiveness and safety of use of the subject device.

Differences between both retinal camera models are shown in Table below.

		Proposed	Predicate
Device Name		CR-2 AF	CR-2 Plus AF
510(k) Submitter [Number]		Canon Inc. K201122	Canon Inc. [K123208]
Product Code		HKI	HKI
Indications for Use		The CR-2 AF is intended to be used for taking digital images of the retina of the human eye without mydriatic.	The CR-2 Plus AF is intended to be used for taking digital images of the retina of the human eye without mydriatic. The CR-2 Plus AF has the following photography modes: color, red free, cobalt digital and fundus autofluorescence (FAF).
Device design			
Light source	Observation	Infrared LED	Infrared LED
	Flash	White LED	Xenon tube
Angular field of view		45/43 ° (digital magnification) (35°when S.P switch is ON)	45/43 ° (digital magnification) (35°when S.P switch is ON)
Actual image size		cp13.7 mm (on sensor array)	cp13.7 mm (on sensor array)
Min. diameter of pupil required		cp4mm (cp3.3mm when S.P switch is ON)	cp4mm (cp3.3mm when S.P switch is ON)
Working distance (WD)		35mm	35mm
Focusing and Photographing		Focusing by aligning the split lines automatically and photographing automatically	Focusing by aligning the split lines automatically and photographing automatically
Switching function		Automatically Switching function from anterior segment to fundus after anterior segments is aligned.	Automatically Switching function from anterior segment to fundus after anterior segments is aligned.
Photography mode		color, red free, cobalt digital and infrared for anterior segment	color, red free, cobalt digital and fundus autofluorescence (FAF)
Anterior segment		Observation and capture	Observation
Eye fixation lamp		Internal (during observation of eye front image and retinal image), External	Internal (during observation of eye front image and retinal image), External
External dimensions		W305×D500×H473mm	W305×D500×H513mm
Weight		Approx.15kg	Approx.19.9kg
Control software		Selectable from the followings: Retinal imaging control software; Non-myd RC Capture Utility	Retinal imaging control software

Performance Data

Non-clinical tests including Electrical safety, Electromagnetic Compatibility, Performance testing, and Software Verification and Validation were conducted to evaluate safety and effectiveness of the CR-2 AF. The CR-2 AF complies with the Recognized Consensus Standard, specifically ANSI/AAMI ES 60601-1, IEC 60601-1-2, IEC 60601-1-6, ISO 15004-1, ISO 10940 and ANSI Z80.36. A qualitative assessment of the function of the anterior segment infrared image for CR-2 AF camera has been performed. The contact parts with patient in the CR-2 AF are the same materials as those used in the predicate device CR-2 Plus AF (K123208) and have been evaluated according to ISO10993 series that is concluded to have no new biocompatibility concern. The software was validated according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005).

Conclusion

Based on the performance data, identical intended use and functional technological characteristics and the similarities in functional design, the proposed CR-2 AF is substantially equivalent to the CR-2 Plus AF (K123208) and does not raise any new questions regarding safety and effectiveness.