Kowa Company, Ltd.
Nariaki Morita
Manager of Development Management Dept
3-1, Chofugaoka 3-Chome
Chofu, 1820021 JAPAN

Re: K191945
Trade/Device Name: KOWA nonmyd 8
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: July 17, 2019
Received: July 22, 2019

Dear Nariaki Morita:

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 *(if known)*
K191945

Device Name
KOWA nonmyd 8

Indications for Use *(Describe)*
KOWA nonmyd 8 is indicated for true color, infrared and fundus autofluorescent (FAF) imaging of a human retina without the use of a mydriatic agent.

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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510k Summary

a. Owner/Company name, address

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b. Contact

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c. Date prepared

June 17, 2019

d. Name of device

Trade Name:	KOWA nonmyd 8
Regulation description:	Ophthalmic Camera
Regulation number:	21 CFR 886.1120
Product code:	HKI

e. Predicate and Reference Devices

Predicate Device

Trade name:	KOWA nonmyd WX
510(k) number:	K101628
Regulation description:	Ophthalmic camera
Regulation number:	21 CFR 886.1120
Product code:	HKI

Reference Devices

The proposed device is equipped with FAF imaging modality. However, the predicate device does not include such imaging modality. Following device is referred for the feature of FAF imaging.

Trade name:	Canon Digital Camera CR-2 Plus AF
510(k) number:	K123208
Regulation description:	Ophthalmic camera
Regulation number:	21 CFR 886.1120
Product code:	HKI

The forehead rest of the proposed device is identical to the forehead rest of following device;

Trade name:	KOWA nonmyd 7
510(k) number:	K053026
Regulation description:	Ophthalmic camera
Regulation number:	21 CFR 886.1120
Product code:	HKI

The chin rest of the proposed device is identical to the chin rest of the following device;

Trade name:	KOWA DR-1α
510(k) number:	K190573
Regulation description:	Ophthalmic camera
Regulation number:	21 CFR 886.1120

Product code: HKI

f. Description of the device

The KOWA nonmyd 8 is an instrument that enables retinal examination and retinal image capturing using infrared rays without requiring the patients to take any mydriatics. The KOWA nonmyd 8 is used with KOWA VK-2s software (510(k) number is K190056) which is designated filing software installed in a computer and enables to save, register or print the captured images.

The KOWA nonmyd 8 has Color mode and FAF mode for photographing. Those are the functions to capture a normal color image and the Fundus Autofluorescence (FAF) image.

g. Indications for Use Statement

KOWA nonmyd 8 is indicated for true color, infrared and fundus autofluorescent (FAF) imaging of a human retina without the use of a mydriatic agent.

h. Discussion of substantial equivalence

Comparative Information

The KOWA nonmyd 8 is an instrument that enables retinal examination and retinal image capturing using infrared rays without requiring the patients to take any mydriatics. The predicate device can also capture retinal images without mydratic.

Indications for Use Statement

The indications for use statement of the KOWA nonmyd 8 is not identical to that of the predicate device because the KOWA nonmyd 8 is not equipped with stereo imaging modality. The plane retinal images of the predicate device are identical to images using the color mode of the proposed device. The stereo imaging is not essential modality of an ophthalmic camera, nor does it affect safety and effectiveness of the KOWA nonmyd 8.

In addition, the indications for use statement of the KOWA nonmyd 8 does not include storage of the images because the KOWA nonmyd 8 is intended to be used with VK-2s software (K190056) which provides storage function.

Based on above, the differences of the indications for use statement do not alter intended use. Both the proposed and predicate devices are intended for use with retinal image capturing without mydriatic.

Technological characteristics

The proposed and predicate devices have the following same fundamental technologies;

- Capturing non-mydriatic color retinal images
- Small pupil mode
- Alignment and focusing methods
- Observation system

The predicate device has no FAF imaging mode. FAF mode is included in the Canon CR-2 Plus AF (K123208). The proposed device has no stereo mode.

Following table shows comprehensive comparison among the proposed, predicate and Canon CR-2 Plus AF(K123208).

Table 1 Comparison Table

Device Name	KOWA nonmyd 8	KOWA nonmyd WX	Canon Digital Camera CR-2 Plus AF
510(k) number	-	K101628	K123208
Indications for use statement	KOWA nonmyd 8 is indicated for true color, infrared and fundus autofluorescent (FAF) imaging of a human retina without the use of a mydriatic agent.	KOWA nonmyd WX is intended for use with plane and stereo retinal image capturing without mydriatic. The retinal image can be stored to an image filing device through serial interface.	The device is intended to be used for taking digital images of the retina of the human eye without a mydriatic. CR-2 Plus AF has the following photography modes: color, red free, cobalt digital and fundus autofluorescence (FAF).
Function			
Photography mode	Color	Normal*	Color
	FAF	Stereo	Red Free
	Small pupil	Small pupil	Cobalt
			FAF
			Small pupil
Storing and Displaying Images (Software name)	YES (KOWA VK-2s software (K190056))	YES (Portable VK-2 software)	YES (unknown)
Transfer Images to external device	YES	YES	unknown
Retinal camera specification			
Saved Images Format	JPEG	JPEG	unknown
Field of view	45 degree	45 degree for plane image	45 degree

		34 degree for stereo image	
Working distance	Same as KOWA nonmyd WX	30mm	35mm
Working distance detection method	Same as KOWA nonmyd WX	Anterior (Observation) Retinal (Focusing on bright spots)	Anterior (Observation) Fundus (Working distance dots)
Minimum diameter of pupil	Normal mode: φ4.0mm Small pupil mode: φ3.3mm	Normal mode: φ4.0mm Small pupil mode: φ3.5mm	Normal mode: φ4.0mm Small pupil mode: φ3.5mm
Diopter compensation	Same as KOWA nonmyd WX	-32 ~ +35D	-31 ~ +33D
Internal eye fixation Navigation	Same as KOWA nonmyd WX	Fixation target selecting by 11 points	LED Dot Matrix
Camera for observation	1/3 inch CCD camera	1/3 inch CCD camera	Unknown
Observation system	Same as KOWA nonmyd WX	LCD	Camera unit monitor
Focusing	Same as KOWA nonmyd WX	By alignment of the split lines	By alignment of the split lines
Filter for FAF	Present	Not applicable	Present
Observation light Source	Same as KOWA nonmyd WX	Infrared LED lamp	LED
Photographing Light Source	Xenon flash lamp (Max 150W)	Xenon flash lamp (Max 50W)	Xenon tube
Power consumption	Same as KOWA nonmyd WX	150VA	unknown
Dimension			
Dimension	Same as KOWA nonmyd WX	310(W) x 504(D) x 548(H) mm	305(W) x 513(D) x 500(H) mm
Weight	Same as KOWA nonmyd WX	21kg (excluding the attached SLR camera)	19.9kg
Other			
Observation media	Same as KOWA nonmyd	5.7 inch LCD Monitor	unknown

	WX		
Record media	Same as KOWA nonmyd WX	Flash memory card	unknown
Conformed Standards	IEC60601-1 :2005 +A1:2012	IEC60601-1: 2005+A1:2012	unknown
	IEC60601-1-2: 2014	IEC60601-1-2: 2007	
	ANSI Z80.36	ISO15004-2:2007	
	ISO10940:2009	ISO10940:2009	

*Normal mode of the predicate device is equivalent to color mode of the proposed device.

The differences do not alter the intended use of the proposed device nor do they affect the safety and effectiveness of the proposed device relative to the predicate. The performance data to prove the safety and performance of KOWA nonmyd 8 are provided below.

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the KOWA nonmyd 8. The proposed device complies with the IEC60601-1:2005 and IEC60601-1-2:2014.

Biocompatibility

The forehead rest and the chin rest of the proposed device contact intact patient skin for a very short time. The forehead rest of the proposed device is identical to the forehead rest of the KOWA nonmyd 7(K053026) and the chin rest of the proposed device is identical to the chin rest of the KOWA DR-1α(K190573). Nature of body contact and contact duration of the proposed device are identical to those of the reference devices in regard to the forehead rest and the chin rest. We determined that the forehead rest and the chin rest of the proposed device have no new biocompatibility concern.

Software verification and validation testing

The software of the proposed device has been validated according to FDA guidance

entitled “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

Optical radiation safety

KOWA performed estimation of the light hazard and evaluation as to whether the KOWA nonmyd 8 satisfied the requirements of ANSI Z80.36-2016. As a result, the KOWA nonmyd 8 is classified in Group 1 of the continuous wave instrument. Although the output power of photographing of KOWA nonmyd 8 is higher than that of the predicate device, the risk of radiation is low level.

Furthermore, the KOWA nonmyd 8 complies with ISO 10940:2009 as with the predicate device.

Clinical Study

A comparative study regarding FAF images quality was conducted using the proposed and the Canon CR-2 Plus AF (K123208) devices. 8 subjects were accepted for this study. For those subjects, one color (with appropriate strobe intensity) image and one FAF image (with ± 0 strobe intensity) by the Canon CR-2 Plus AF (K123208) were taken. If a doctor determined that the FAF image is not good quality for diagnosis, one more FAF image with appropriate strobe intensity was taken by the Canon CR-2 Plus AF (K123208). And then, for the same subjects, one color (with appropriate strobe intensity) and three FAF images (with ± 0 and with -2 & -1, -1 & +1 or +1 & +2) by the KOWA nonmyd 8 were taken. The best FAF image for diagnosis taken with the KOWA nonmyd 8 was selected. The FAF image from the KOWA nonmyd 8 was evaluated by comparing image quality with the FAF image from the Canon CR-2 Plus AF (K123208).

The KOWA nonmyd 8 were superior or equivalent to the Canon CR-2 Plus AF (K123208) for 6 subjects and were inferior but diagnosable for 2 subjects. Therefore, 75 % images by the KOWA nonmyd 8 were superior or equivalent to the Canon CR-2 Plus AF (K123208).

i. Conclusion

The non-clinical testing demonstrates that performance except FAF imaging of the KOWA nonmyd 8 was comparable to the predicate device and any new concern regarding safety and performance was not raised for the proposed device. The

clinical testing demonstrates that FAF image quality of the proposed device is similar to that of the Canon CR-2 Plus AF (K123208) and no new concern was raised for the proposed device. Based on the information described above, we conclude that the KOWA nonmyd 8 is substantially equivalent to the predicate device.