February 12, 2019

KOWA Co. Ltd. CHOFU
% Ryan Bouchard
VP, Medical Devices
Ora, Inc.
300 Brickstone Square
Andover, MA 01810

Re: K190056
Trade/Device Name: KOWA VK-2s
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: January 9, 2019
Received: January 11, 2019

Dear Ryan Bouchard:

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,

Alexander Beylin -S
2019.02.12 16:15:48 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190056

Device Name
KOWA VK-2s

Indications for Use *(Describe)*

KOWA VK-2s is indicated for acquiring, displaying and storing image data from KOWA's mydriatic and non-mydriatic ophthalmic cameras.

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 summary of the 510(k) premarket notification for the Kowa VK-2s is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

a. Owner Company name, address

Kowa Company Limited
3-1, Chofugaoka 3-chome
Chofu Tokyo 182-0021 Japan

Contact person:

Rinji Kondo
Phone: +81-42-440-7612
Fax: +81-42-440-7618
Email: r-kondo@kowa.co.jp

b. Contact/Application Correspondent

Ryan Bouchard

Ora, Inc.

300 Brickstone Square

Andover, MA 01810

Telephone: (978) 332-9574

Facsimile: (978) 689-0020

E-mail: rbouchard@oraclinical.com

c. Date Updated

February 1, 2019

d. Name of Device

Trade Name:	Kowa VK-2s
Common Name:	VK-2s
Classification Name:	Picture archiving and communication systems
Classification Regulation:	21 CFR 892.2050
Product Code:	NFJ
510(k) Number:	K190056

e. Predicate Devices

Primary: The VK-2s is substantially equivalent to the image management software system Canon Ophthalmic Software Platform RX cleared in K173689. As explained in more detail below, the Canon Ophthalmic Software Platform RX and the VK-2s software both have the same indications for use, similar principles of operation, and similar technological characteristics.

Secondary: The VK-2s is substantially equivalent to the KOWA portable VK-2 in the KOWA nonmyd α-DIII cleared in K083387. The KOWA portable VK-2 and the VK-2s software both have the same intended use, similar principles of operation, and similar technological characteristics.

f. Device Description

The VK-2s consists of five types of software models including the:

- VK-2s Standard
- VK-2s VX-20
- VK-2s nonmyd
- VK-2s nonmydWX
- VK-2s Viewer

The VK-2s Standard, VK-2s VX-20, VK-2s nonmyd, and VK-2s nonmydWX are all software executed on a capture PC. The software acquires images from a retinal camera that the control software captures and puts on the capture PC. The software acquires images of the eye, stores images and processes images. The software displays acquired and processed images which are stored in a Server's database. The only difference between these four software programs are the devices that are supported for providing images:

VK-2s Standard

This software only supports images from:

- KOWA VX series cameras,
- KOWA nonmyd series cameras
- and supports file import.

VK-2s VX-20

This software only supports images from:

- KOWA VX-20 series cameras,
- and supports file import.

VK-2s nonmyd

This software only supports images from the KOWA nonmyd series cameras.

VK-2s nonmydWX

This software only supports images from the KOWA nonmydWX cameras.

VK-2s Viewer

This is a software executed on a viewer PC. This software stores images, processes images and displays acquired and processed images which are stored in a server database. This software does not support image capture.

The VK-2s software also takes advantage of three software packages included with the VK-2s. These are:

VK-Montage Software

This software allows the operator to create montages using multiple images

VK-Scan

VK Scan is software which can be used to import images located in a specified folder.

VK-DDV

The detailed database viewer provides advanced searching, viewing, image processing, printing, and reporting for your VK-2s database.

g. Indications for Use

KOWA VK-2s is indicated for acquiring, displaying and storing image data from KOWA's mydriatic and non-mydriatic ophthalmic cameras.

h. Statement of Substantial Equivalence

Kowa's VK-2s is substantially equivalent to the image management software, Canon Ophthalmic Software Platform RX cleared in K173689. The VK-2s has the same indications for use, follows similar principles of operation, and has similar technological characteristics as the previously cleared software predicate device**.**

The VK-2s and the Canon Ophthalmic Software Platform RX are both ophthalmic image archiving and communications systems that collect, store, and manage digital images of the eye and both are indicated for use with mydriatic and non-mydriatic cameras.

In comparison between the KOWA VK-2s and the Canon Ophthalmic Software Platform RX there are differences in function in the following areas: (differences are in **bold**).

Table 1: Comparison of KOWA VK-2s to Canon Ophthalmic Software Platform RX

	Proposed Device	Predicate Device
Model	KOWA VK-2s	Ophthalmic Software Platform RX
Device Design		
Type of Retinal Camera image	Color **Montage** FAF FA	Color - FAF FA
View Image	Single View Full Screen (Frame Size) Both Eyes Multiple Images **Loop** -	Single View Full Screen (Frame Size) Both Eyes Comparison - **Progression**
Drawing Function	-	**Supported**
Image Processing	**Sharpen Image** **Gamma Process** Zoom RGB Filters **Enhance Image** Contrast **Analysis of RGB Color** **Negative Image** **Edge Enhancement** **Histogram Chart** **Flip Image** - - -	- - Zoom RGB Filters - Contrast - - - - - **Cobalt** **Emboss** **Redfree**
Image Measurement	C/D Ratio **Measure Distance** **Measure Angle**	C/D Ratio - -

The KOWA VK-2s functions of montage image, loop view, the image processing functions of sharpen image, Gamma process, enhance image, analysis of RGB color, negative image, edge enhancement, histogram chart and flip image and the measurement functions of measure distance and measure angle are not offered in the Canon device. The Canon Ophthalmic Software Platform RX device offers view progression, a drawing function, and the image processing functions of cobalt, emboss, and redfree which are not present in the VK-2s.

Kowa's VK-2s is substantially equivalent to the KOWA portable VK-2 software in the KOWA nonmyd α-DIII cleared in K083387. The VK-2s has the same intended use, follows similar principles of operation, and has similar technological characteristics as the previously cleared software included in the predicate device**.**

The VK-2s and the KOWA portable VK-2 software in the KOWA nonmyd α-DIII are both ophthalmic image archiving and communications systems that collect, store, and manage digital images of the eye and are both are indicated for use with non-mydriatic cameras.

In comparison between the KOWA VK-2s and KOWA portable VK-2 in the KOWA nonmyd α-DIII there are differences in function in the following areas: (differences are in **bold**).

	Proposed Device	Predicate Device
Model	KOWA VK-2s	KOWA nonmyd α-DIII
Device Design		
Type of Retinal Camera software used in conjunction with	**Mydriatic** Non-mydriatic	 Non-mydriatic
Type of Retinal Camera image	Color Montage FAF **FA**	Color Montage FAF -
Image Processing	Sharpen Image Gamma Process Zoom RGB Filters Enhance Image Contrast Analysis of RGB Color Negative Image **Edge Enhancement** **Histogram Chart** Flip Image	Sharpen Image Gamma Process Zoom RGB Filters Enhance Image Contrast Analysis of RGB Color Negative Image - - Flip Image

The KOWA VK-2s functions of FA image and the image processing functions of edge enhancement and histogram are not offered in the KOWA portable VK-2 in the KOWA nonmyd α-DIII device.

The differences between the KOWA VK-2s and the two predicate software devices include the addition of Edge Enhancement and Histogram chart to the image processing of the VK-2s. The VK-2s does not support the image processing functions of cobalt, emboss and redfree and does not support the Drawing function which are functions of the Canon Ophthalmic Software Platform RX.

The differences between the subject device and the predicate devices are considered to be minor and do not raise new questions of safety or effectiveness. The VK-2s is as safe and effective as the predicate devices, and thus may be considered substantially equivalent.

i. Performance Data

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

j. Conclusions

Kowa's VK-2s is as safe and effective as the previously cleared Canon Ophthalmic Software Platform RX cleared in K173689 and the portable VK-2 component of the Kowa nonmyd α-DIII (K083387). The VK-2s has the same intended use and similar indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device and is therefore substantially equivalent**.**