June 4, 2019

Kowa Company, Ltd.
Nariaki Morita
Manager of Development Management Dept.
3-1 Chofugaoka 3-Chome Chofu City
Tokyo, 182-0021 JAPAN

Re: K190573
Trade/Device Name: KOWA DR-1α
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: December 14, 2018
Received: March 6, 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,

Bradley S. Cunningham -S

for Malvina B. Eydelman, M.D.
Director
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)*
K190573

Device Name

KOWA DR-1α

Indications for Use *(Describe)*

The KOWA DR-1α is an ocular surface interferometer, which is an ophthalmic imaging device that is intended for use by physician in adult patients to observe and record a video image of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K190573

Kowa Company, Ltd.

Chofu Factory

510k Summary

A. Owner/Company name, address

Kowa Company, Ltd.

3-1, Chofugaoka 3-Chome
Chofu Tokyo, JAPAN 182-0021

Phone: +81-42-440-7612
Fax: +81-42-440-7618

B. Contact

Nariaki Morita
Kowa Company, Ltd.
Medical Device Division
3-1, Chofugaoka 3-Chome
Chofu Tokyo, JAPAN 182-0021
Phone: +81-42-440-7627
Fax: +81-42-440-7618

Email: n-morita@kowa.co.jp

C. Date prepared

December 14, 2018

D. Name of device

Trade Name:	KOWA DR-1α
Regulation Number:	21 CFR 886.1120
Regulation Name:	Ophthalmic Camera
Regulatory Class:	II
Product Code:	HKI

E. Predicate and Reference Devices

Predicate Device

510(k) number:	K091935
Trade name:	LipiView Ocular Surface Interferometer
Regulation Number:	21 CFR 886.1120
Regulation Name:	Ophthalmic Camera
Regulatory Class:	II
Product Code:	HKI, HJO

The predicate device is hereinafter called "the LipiView" in this submission.

Reference Device

The forehead rest of the proposed device is identical to the forehead rest of the reference device. Both proposed and reference devices are the ophthalmic cameras and a patient contacts the forehead rest for a very short time. In addition, both forehead rests are disinfected with rubbing alcohol.

510(k) number:	K112330
Trade name:	KOWA VX-20
Regulation Number:	21 CFR 886.1120
Regulation Name:	Ophthalmic Camera
Regulatory Class:	II
Product Code:	HKI

F. Description of the device

The KOWA DR-1*a* is ocular surface interferometer, which is an ophthalmic imaging device that is intended for use by a physician in adult patients to observe and record a video image of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

This instrument is intended to observe and record a video of the interference image with illuminating white light on the tear film layer. Users can replay the recorded image on the instrument's monitor to observe the condition of the tear film layer

In addition, using the image currently being replayed, users can measure the duration time by specifying 2 different point of time. This instrument has a function that allows users to output a video or a still image clipped from the video to an external personal computer.

G. Indications for Use Statement

The KOWA DR-1*α* is an ocular surface interferometer, which is an ophthalmic imaging device that is intended for use by physician in adult patients to observe and record a video image of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

H. Discussion of substantial equivalence

Comparative Information

Both the KOWA DR-1*α* and the predicate device are an ocular surface interferometer.
The indications for use statement of the KOWA DR-1*α* is virtually the same as for the LipiView. The differences of the indications for use statement are minor and do not alter the intended use.

Fundamental technology as ocular surface interferometer is similar between the two devices as shown below:

Technological Principle of the LipiView

The LipiView operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The patient's eye is positioned in front of an illumination source directed toward the tear film on the corneal surface. Light from the illumination source passes through the outer lipid layer of the tear film and is secularly reflected into a camera. The light reflecting through back the lens in the camera forms an interference pattern, called an "interferogram". The computer system captures a video image file that is recorded over time since the interference pattern changes as the lipid layer of the tear film is distributed across the cornea during blinking. The video image of the ocular surface may be viewed on the computer screen display and in a printed report.

Technological Principle of the KOWA DR-1*α*

The KOWA DR-1*α* is intended to observe and record a video of the interference image with illuminating white light on the tear film layer. Users can replay the recorded image on the instrument’s monitor to observe the condition of the tear film layer.

The surface layer of the tear film layer is called the tear film lipid layer. It is a thin layer of approximately 100nm thick. When white light is irradiated on the tear film surface, several interference patterns appear by difference in two specular reflection light paths obtained between the surface and the back of the lipid layer. For the reflection light at the tear film layer, the KOWA DR-1*α* uses two polarizer (parallel), only the reflected image of the illumination light is captured by the camera, and the external light is not taken into the camera. As a result, background image such as iris and sclera does not appear and the interference image of the tear film layer can be efficiently observed.

The similarities between KOWA DR-1*α* and LipiView are:

- Intended use
- Capability to record interference image
- Camera resolution
- Illumination source
- Illumination area
- Interference image
- Power supply

The differences between KOWA DR-1*α* and LipiView are:

- Image resolution
- Dimension
- Weight
- Power consumption

The differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. The performance data to prove the safety and performance of KOWA DR-1*α* are provided in section of **Performance data** of this summary below.

Following table shows comparison between the proposed and predicate devices.

Table 1. Comparison Table

	Proposed device	**Predicate device**
Device name	KOWA DR-1*a*	LipiView Ocular Surface Interferometer
510(k) number	K190573	K091935
Indications for use statement	The KOWA DR-1*a* is an ocular surface interferometer, which is an ophthalmic imaging device that is intended for use by physician in adult patients to observe and record a video image of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.	The LipiView Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.
Performance Specifications		
Illumination area	Wide type (low magnification) Diameter: 8.0 mm Height: 7.2 mm Narrow type (high magnification) Width: 3.4 mm Height: 2.5 mm	Width: 9.5 mm Height: 4.6 mm
Image resolution	45.3 line pairs / mm (Narrow) 18.0 line pairs / mm (Wide)	14.3 line pairs / mm
Other Specifications/Characteristics		
Camera resolution	640 x 480 pixels	Same
Illumination source	White LED	Same
Dimension	290(W) x 365(D) x 455(H) mm	430(W) x 720(D) x 430(H) mm
Weight	14 kg	24.95 kg
Power supply	AC100-240V, 50/60Hz	Same
Power consumption	70VA	80VA

I. Performance data

Dimension, weight and power consumption of the KOWA DR-1*a* are less compared to the LipiView. Such differences do not result in lower performance as shown in the comparison table. The comparison of quality of images obtained from the proposed and predicate devices was conducted because of the differences of Illumination area and Image resolution.

Performance Comparison with the Predicate Device

Test was performed to evaluate performance of the KOWA DR-1*a* compared to the LipiView regarding Illumination area, Image resolution and Interference image.

Test results indicated that the KOWA DR-1*a* has similar Illumination area and Interference image to the LipiView and higher Image resolution than the LipiView.

The following performance tests were conducted in support of the substantial equivalence determination.

Testing for Repeatability

The repeatability was investigated by comparing the hue values measured with three units of DR-1α and by three examiners. Each measurement was repeated 5 times. The hue values obtained did not exceed the acceptance range.

Optical Radiation Safety

KOWA performed estimation of the light hazard and evaluation as to whether the KOWA DR-1*a* satisfied the requirements of ANSI Z80.36-2016. As a result, the KOWA DR-1*a* is classified in Group 1 of the continuous wave instrument. Therefore, the KOWA DR-1*a* complies with ANSI Z80.36-2016.

EMC and Electrical Safety

EMC and Electric safety were confirmed in accordance with IEC 60601-1-2:2007 and IEC 60601-1:2012, respectively.

Biocompatibility

The forehead rest and the chin rest of the proposed device contact intact patient skin for a very short time. The biocompatibility evaluation for those parts were conducted in accordance with ISO 10993-1:2009 and referencing FDA guidance entitled "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The following tests were conducted to evaluate biocompatibility of the proposed device:

- Cytotoxicity
- Sensitization
- Irritation

Software validation

The software of the proposed device has been validated according to FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

J. Conclusion

Based on the information described above, KOWA DR-1*a* is substantially equivalent to the predicate device in technical characteristics, operating principles and performance characteristics for the intended uses in the stated medical specialties. There are no new safety and effectiveness issues being raised.