November 21, 2022

Kowa Company, Ltd.
Nariaki Morita
Manager of Quality Assurance Section
3-1, Chofugaoka 3-Chome
Chofu-shi, Tokyo 1820021
Japan

Re: K222372
Trade/Device Name: Kowa SL-19
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: October 13, 2022
Received: October 13, 2022

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 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)*
K222372

Device Name
KOWA SL-19

Indications for Use *(Describe)*
KOWA SL-19 is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye 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

a. Owner/Company name, address

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b. Contact

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c. Date prepared

November 15th, 2022

d. Name of device

Trade Name:	KOWA SL-19
Regulation description:	Slit lamp
Regulation number:	21 CFR 886.1850
Product code:	HJO

e. Predicate and Reference Devices

Predicate Device: KOWA SL-17

510(k) number K133755

Regulation description: Slit lamp

Regulation number: 21 CFR 886.1850

Product code: HJO

f. Description of the device

The KOWA SL-19 is a non-invasive ophthalmic device that is able to illumination, magnification and observation of the human eye.

Illumination light that emitted from a white light source is applied to the eyeball, Refractive media, Eye Anatomy, Ocular Adnexa, Iris, etc. are magnified and observed with a binocular microscope. Fluorescence of the cornea, conjunctiva, etc. can be observed by irradiating background illumination light and irradiating blue illumination light with a built-in light source.

The background White LED function is added to the KOWA SL-19.

The blue filter with white LED for the predicated device is removed, and this function is replaced by blue LED for the KOWA SL-19.

Duration of illumination is lengthened from 140 min to 360 min from predicate device to the KOWA SL-19 due to replace the battery type from AAA battery to AA battery.

g. Indications for Use Statement

KOWA SL-19 is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

h. Discussion of substantial equivalence

The proposed device KOWA SL-19 is an instrument of handheld slit-lamp microscope that enables projects slit light onto the human eye and magnify with a binocular microscope and is using for observation and inspection of human eye.

Indications for use of the KOWA SL-19 is identical to that of the predicate device.
Technological characteristics

The KOWA SL-19 and predicate device have the following same fundamental technologies:

- Observation of the human eye
- Function and principle parts

The difference between the proposal device KOWA SL-19 and the predicate device KOWA SL-17 is as follows.

- The background White light function is added.
- Blue light is replaced from filter with white LED to the blue LED
- Duration of illumination is lengthened from 140 min to 360 min.

Following are discussion regarding differences and substantial equivalence between the proposed and predicated device.

Background White light

This Background White LED is conformed to the light hazard standard ANSI Z80.36.2016 then does not raise any safety concern. Also this function does not affect the efficacy of the slit lamp standards ANSI Z80.37.2017 but simply light to whole eye then does not affect any efficacy concern.
Therefore, this new function does not raise any safety and efficacy concern.

Filter

The blue LED for the proposed device is conformed to ANSI Z80.36.2016 then does not raise any safety concern. Also the both the proposed blue LED and the predicated bule filter with white LED are almost identical excitation wave length that is within 400 to 500 nm conformed to fluorescein excitor filter, then this function does not affect any efficacy concern. Therefore this function does not raise any safety and efficiency concern.

Duration of illumination

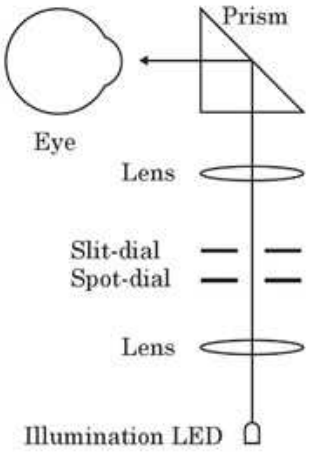
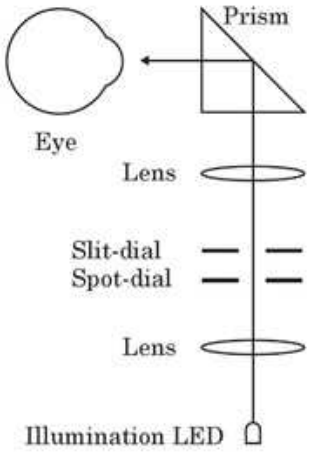
This change simply adds convenience for user and conformed the safety standard IEC60601-1:2005+A1:2012 and IEC60601-1-2:2014. Also this duration of illumination does not affect any efficacy of slit lamp. Therefore this function does not raise any safety and efficacy concern.

Following table shows comparison between the KOWA SL-19 and predicate device.

Table 1 Comparison Table

	Proposed device	Predicate device	Note
Device Name	KOWA SL-19	KOWA SL-17	
510(k) number	K222372	K133755	
Indications for use or Scope	KOWA SL-19 is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.	KOWA SL-17 is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.	Identical

Slit lamp function, Optical path and principal parts			
Illumination light source	White LED		Identical
Background light	White LED and Blue LED	-	Different
Filter	-	Built-in blue filter	Different
Slit selection	Turret		
Slit length	1 mm, 5 mm, 12 mm, and from 1.5 to 12mm continuously	Three selection (1, 5, 12mm)	Similar
Slit width	Three selection (0.1, 0.2, 0.8mm)		Identical
Spot	φ1, φ5, φ12mm and shapes of ellipse		Identical
Light intensity	Adjustable continuously by the software		Identical
Slit projection angle	60 degree for Horizontal		Identical
Duration of illumination	360 minutes (When used the 3 x AA batteries (Ni-MH) of 1900mAh, and the room temperature is 25 degrees Celsius)	140 minutes (When used the 4 x AAA batteries (Ni-MH) of 750mAh, and the room temperature is 25 degrees Celsius)	Different
Electric rating	DC 3.0 to 4.8V / 3.6VA	DC 4.8 to 6.4V / 3.6 to 4.5VA	Similar
Battery type	3pcs of AA batteries (Alkaline or Ni-MH)	4pcs of AAA batteries (Alkaline or Ni-MH)	Similar
Microscope function and principal parts			
Angle of convergence	13 degree		Identical
Magnification	10x / 16x		Identical
Reticles	Built-in both oculars		Identical
Magnification change	10x and 16x Magnification is changed through movement objectives to two positions.		Identical
Range of interpupillary distance adjustment	55mm to 72mm	50mm to 72mm	Similar
Range of examiner's dioptric protection adjustment	-8D to +5D		Identical

Dimension			
Dimension (W)x(D)x(H) (mm)	107x197x238	Microscope: 95 x 220 x 220 Stand: 105 x 200 x 50	
Weight	620g (batteries are not included)	Microscope:745g (batteries are not included) Stand: 655g	
Performance Testing			
Performance for Slit-lamp	IEC60601-1:2005+A1:2012	IEC60601-1:2005	Similar
	IEC60601-1-2:2014	IEC60601-1-2:2007	Similar
	ANSI Z80.36-2016	ISO15004-2:2007	Identical
	ANSI Z80.37-2017	ISO10939:2007	Identical
Biocompatibility for forehead rest	Same forehead rest part as used in KOWA SL-17. The biocompatibility of the forehead component was assessed per FDA Biocompatibility guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process’” recommendations.		Identical
Software	Guidance for Industry and FDA Staff-Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices		Identical
Optical path			
Optical path			Identical

i. Performance Testing

Following are listed all standard that is performed.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the KOWA SL-19. The proposed device complies with the IEC60601-1:2005+A1:2012 and IEC60601-1-2:2014.

Biocompatibility

The forehead rest of the proposed device is a surface device with limited (≤24 hrs.) contact with intact skin. The forehead rest of proposed device is same as the forehead rest of the predicate device that has the same nature and duration of the tissue contact. There are 4,200 predicate devices sold in the US and there were no adverse events reported (e.g., allergy) related to the forehead rest of the predicate device.

Furthermore, the biocompatibility of the forehead rest of the proposed device was assessed per FDA Biocompatibility guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process’ “ recommendations.

Software

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”. The report of software of the proposed device are described in Section 18_Software.

Optical radiation safety

KOWA performed estimation of the light hazard and evaluation as to whether the KOWA SL-19 satisfied the requirement of ANSI Z80.36-2016. As a result, the KOWA SL-19 is classified in Group 2 of the continuous wave instrument. Although the output power of illumination of KOWA SL-19 is higher than that of the predicate device, the risk of radiation is low level.

Performance testing for Slit-Lamp Microscopes

The KOWA SL-19 conform to ANSI Z80.37.2017 as well as the predicate device conform to ISO 10939:2007

j. Conclusion

There are some differences between the proposed and predicate devices. As discussed above, all differences do not raise any safety and efficacy concern.
Based on the information described above, we conclude that KOWA SL-19 is substantially equivalent to the predicate device.