December 21, 2017

Chongqing Kanghua Ruiming S&T Co., Ltd.
Xi You
Production Manager
No.5, Road1, Tongjiaxi Industrial Park, Beibei
Chongqing, 400070 CHINA

Re: K171877
Trade/Device Name: SLM-1ER, SLM-2ER, SLM-3ER
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: November 1, 2017
Received: November 1, 2017

Dear Xi You:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Bradley S. Cunningham -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171877

Device Name
KH Ophthalmic Slit-lamp Microscope
Model: SLM-1ER, SLM-2ER

Indications for Use *(Describe)*
The KH Ophthalmic Slit-lamp Microscope is an AC-powered slitlamp biomicroscope 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 affects 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.

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.

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510(k) SUMMARY (K 171877)

KH Ophthalmic Slit-lamp Microscope

1. Submitter's Information

The submitter of this special pre-market notification is:

Name:	Chongqing Kanghua Ruiming S&T Co., Ltd.
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Contact Person:	Xi You
E-mail:	doumeki2007@163.com
Date summary prepared:	April 15, 2017

2. Device Identification

Device Trade Name:	KH Ophthalmic Slit-lamp Microscope Model: SLM-1ER, SLM-2ER
Classification Name	AC- Powered Slit-Lamp Biomicroscope
Regulation Number:	21 CFR 886.1850
Regulation Name:	AC Powered Slit lamp Bio-microscope
Regulation Class:	II
Product Code:	HJO

3. Predicate Devices

- Model: SLM-1ER, SLM-2ER, the predicate cited is the Keeler Slit Lamp H-Series of the same instrument:

Device Trade Name:	Keeler Slit Lamp H- Series
510(k) Number;	K131589
Common Name	AC Powered Slit lamp Bio-microscope
Class:	II
Classification Panel:	86
Product Code:	HJO
Regulation Number:	886.1850

4. Device Description

The KH Ophthalmic Slit-lamp Microscope is an AC-powered device that is a microscope intended for use in eye examination that projects into a patient's eye through a control diaphragm a thin, intense beam of light. The KH Ophthalmic Slit-lamp Microscope is composed of the following components: microscope unit, illumination unit, base unit, chinrest, and table and power unit. The slitlamp biomicroscope is used for the observation of the eye. It has an illumination unit to illuminate the eye, and a binocular stereoscopic microscope to zoom and observe patient's eyes, and also can observe the three-dimensional image.

5. Intended Use / Indications for Use

The KH Ophthalmic Slit-lamp Microscope is an AC-powered slitlamp biomicroscope 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 affects the structural properties of the anterior eye segment.

6. Comparison to predicate device

Feature	***H-Series Slit Lamp [K131589]***	***KH Ophthalmic Slit-lamp Microscope***	***Discussion***
Intend use	As stated	As stated	No changes
Bio-microscope			
Bio-microscope	Galilean converging binoculars with detachable eyepiece head	• SLM-1ER, Converging binoculars with detachable eyepiece head • SLM-2ER, Galilean converging binoculars with detachable eyepiece head	As head can be separated from the body, intervention of module does not change these elements
Digital Camera Module	Not fitted	• SLM-1ER, SLM-2ER: Not fitted	Same

Image capture button	Not fitted	• SLM-1ER, SLM-2ER: Not fitted	Same
Camera Exposure Buttons	Not fitted	Not fitted	Same
Slit Lamp illumination Options	6VDC 20W halogen bulb / LED	12V/50W halogen bulb	Required for slit lamp illumination with some light used for background lighting
Background Illumination adjuster	Not fitted	• Not fitted	Same
Background Light Source Options	Not fitted	• Not fitted	Required for higher background light output but still conforms to requirements of 15004-2 Photo toxicity with slightly longer exposure time.
Background lighting duty cycle - halogen bulb option only	Not applicable	50% duty cycle at maximum brightness.	Ensures body of light source does not exceed 62.3 °C limit demanded by IEC 60601-1 compliance
Duration of illumination	Maximum examination times according to ISO 15004-2 and ISO 10939	Maximum examination times according to ISO 15004-2 and ISO 10939	As a result of photo-toxicity testing to ISO 15004-2 maximum exposure increased from 13 to 17 minutes for bulb option (LED maximum exposure is unchanged at 12.5 minutes).
Input voltage	AC 100-240 V, 50/60 Hz	AC 110 V, 50/60 Hz	Same

Power output	30 VA	50VA (4.2 A)	Required for change to 12V bulb

7. Non-Clinical testing

Safety and EMC:

Safety and EMC test was performed in according to the

- IEC60601-1:2005 + CORR.1(2006)+CORR.2(2007)+AM1(2012) or IEC 60601-1:2012
- IEC 60601-1-2:2007 Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.

Biocompatibility :

Biocompatibility testing was performed to evaluate the biocompatibility of the contact materials in accordance with ISO 10993-1:2009, the device passed each biocompatibility test indentified below:

- Cytotoxicity testing in according to ISO 10993-5:2009
- Skin irritation testing in according to ISO 10993-10:2010
- Vaginal irritation testing in according to ISO 10993-10:2010
- Sensitization testing in according to ISO 10993-10:2010

Performance Data:

The following bench testing was conducted in order to support substantial equivalence:

- ISO 15004-1:2006 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments. The testing found that the product met the requirements of ISO 15004-1:2006.
- ISO 15004-2:2007 Ophthalmic Instruments - Fundamental requirements and test methods - Part 2: Light hazard protection. The testing found that the device is a Group 2 instrument.
- ISO 10939:2007 Ophthalmic Instruments - Slit-lamp microscopes found that the KH OPHTHALMIC SLIT-LAMP MICROSCOPE complies with the requirements of the standard.
- IEC 62471:2006 Photobiological safety of lamps and lamp systems

8. Conclusions:

The KH Ophthalmic Slit-lamp Microscope (Model: SLM-1ER, SLM-2ER) is substantially equivalent to the predicate device in indications for use and construct, Safety and EMC testing to IEC60601-1 and IEC 60601-1-2, and performance testing to ISO 15004-1, ISO 15004-2 and ISO 10939, Based on the information provided in this submission, the KH Ophthalmic Slit-lamp Microscope(Model: SLM-1ER, SLM-2ER) is substantially equivalent to the predicate devices(K131589).