DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 21, 2017

Suzhou Kangjie Medical Inc.
% Di Wu, Ph.D.
Regulatory Affairs Consultant
DIWU Regulatory
3440 Indian Queen Lane, Rear
Philadelphia, PA 19129

Re: K162778
Trade/Device Name: Portable Slit Lamp Microscope
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: May 25, 2017
Received: May 30, 2017

Dear Dr. Di Wu:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

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)*

K162778

Device Name
Portable Slit Lamp Microscope Model KJ5S

Indications for Use *(Describe)*
Portable Slit Lamp Microscope Model KJ5S is intended for use in the examination of the anterior and posterior segment of the eye.

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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Date prepared July 13, 2017

Submission Sponsor (Manufacturer):

Suzhou Kangjie Medical Inc.
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Submission Correspondent (Agent):

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Trade/Device Name:

Portable Slit Lamp Microscope
Model KJ5S

Common or Usual Name: Slit Lamp Microscope
Device Class: II
Classification Name: AC-Powered Slitlamp Biomicroscope
Regulation Number: 21 CFR 886.1850
Product Code: HJO
Review Panel: Ophthalmic

Predicate Device:

- K131711, SUZHOU 66 VISION TECH CO., LTD
  YZ3 PORTABLE SLIT LAMP

Device Description:

Portable Slit Lamp Microscope
Model KJ5S

The Portable Slit Lamp Microscope is a hand held converging stereomicroscope system powered by rechargeable batteries.

The illumination system and fixation targets are activated using a single/double click trigger located on the rear of the grip/handle. A rheostat located below the eyepieces on the front of the grip /handle is used to increase or reduce the light intensity.

Environment of Use: healthcare facility/hospital
Duration and type of contact: less than 24 hours, surface device

Intended Use:

Portable Slit Lamp Microscope Model KJ5S is intended for use in the examination of the anterior and posterior segment of the eye.

Comparison to Predicate Device:

Refer to the Comparison Table on Pages 4 and 5.

Discussion of Non-Clinical Tests Performed:

The performance tests were conducted:

IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

ISO 15004-1, Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments

ISO 15004-2, Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection

ISO 10939, Ophthalmic instruments — Slit-lamp microscopes

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International

Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

ISO 10993-1, Biological Evaluation of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process. (Biocompatibility)

ISO 10993-5, Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)

ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)

IEC 62133, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

Discussion of Clinical Tests Performed:

None

Conclusion:

The subject device has the same intended uses and indications, similar technological characteristics, and principles of operation as its predicate device. The minor differences between the subject device and its predicate devices raise no new issues of safety or effectiveness. Thus, the subject devices are substantially equivalent to its predicate devices.

Comparison Table

KJ5S Slit Lamp Microscope vs. K131711

Descriptive Information	Proposed Device	Predicate Device
510(k) Number	**K162778**	**K131711**
Manufacturer	Suzhou Kangjie Medical Inc.	66 Vision Tech Co., Ltd.
Proprietary or Model Name	KJ5S portable slit lamp microscope	YZ3 Portable Slit Lamp microscope
Indications for Use	Same	Same
Flammability of materials near the light source	NONE	NONE
Maximum temperature of parts of the device held by the operator or accessible to the patient	Maximum temperature of parts of the device held by the operator: - Eyepiece: 35° - Grip: 35 ° - Slit width control ring: 35° Maximum temperature of parts of the device accessible to the patient: Forehead rest 35°	Same
Brightness controls	Maximal Illumination ≥12000Lx	Maximal Illumination ≥30000Lx
Operating temperature	10° to 35°	Same
Slit Width	0 to 10mm continuously adjustable	0 to 12mm continuously adjustable
Slit Length	1mm, 3mm, 5mm, 10mm	0.2mm, 1mm, 2mm, 12mm
Illumination field diameter	1mm, 3mm, 5mm, 10mm	0.2mm, 1mm, 2mm, 12mm
Radial movement of the slit light illumination relative to the microscope axis	Horizontal ± 30°	Same
Stereo angle	13°	Same
Light sources	White LED Single Light Source	Same
Pupil-distance	48 to 72mm	50 to 75mm
Eye piece	10X, 16X	Same
Objective	1X	Same
Total magnifications	10X, 16X(Optional)	Same
Filter	Heat-absorption, Cobalt blue, Red-free, Gray	Cobalt blue, Red-free, Color Temperature Compensation

Comparison Table

Descriptive Information	Proposed Device	Predicate Device
510(k) Number	**K162778**	**K131711**
Illumination rotation angle	Horizental±30°	Same
Working distance	80mm	60mm
Power	7.4V 680mAh Li Battery，Rechargeable	7.4V 2200mA Li Battery，Rechargeable
Working time	5-6 hours	2.5 hours
Net Weight	750g	900g