November 22, 2018

Chongqing Sunkingdom Medical Instrument Co Ltd
Joy Tse
Sales Director
1012, Block A of China Resource Center
No.55 of XieJiaWan,JiuLongPo
Chongqing, 400050 Cn

Re: K182306
Trade/Device Name: Sunkingdom Slit Lamp
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: August 24, 2018
Received: August 24, 2018

Dear Joy Tse:

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,

Bradley S. Cunningham -A

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)*
K182306

Device Name
Sunkingdom Slit Lamp LS-1A,LS-1B

Indications for Use *(Describe)*
The Chongqing Sunkingdom Slit Lamp LS-1A, LS-1B are AC---powered slit lamp Biomicroscopes 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.

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510(k) Summary

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

Submitter(510K Owner): Chongqing Sunkingdom Medical Instrument Co.,Ltd
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Dateof Preparation: August 24,2018

Proprietary Name: Sunkingdom Slit LampLS-1A,LS-1B

Common or usual name: AC- Powered Slit-Lamp Biomicroscope

ClassificationName: Biomicroscope, Slit-Lamp,AC-Powered
21 C.F.R. 886.1850
Class II

Productcode: HJO

Predicate Devices:

Predicate devices	Suzhou 66 Vision Tech YZ Slit Lamp YZ3
Manufacturer	Suzhou 66 Vision-Tech Co.,Ltd
K#	K131711

Device Description:

Sunkingdom slit lamp LS-1A, LS-1B are an AC-powered slit lamp bio-microscope 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 affects the structural properties of the anterior eye segment.

An AC-powered Slit lamp Bio-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.

Components: The optical body, movement mechanism, illumination system, portable handle, power supply.

Intended Use/ Indication for use

The AC-powered slit lamp bio-microscope 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 affects the structural properties of the anterior eye segment.

Substantial Equivalence

The Portable slitlamp LS-1A,LS-1B is substantially equivalent to the predicate device Suzhou 66VisionTech YZ Slit LampYZ3 as they have the exactly same indication for use, which is to examine the anterior eye segment for diagnostic purposes. Also Sunkingdom slit lamp use similar technology and perform similar functions to provide the physician with the necessary information to make a diagnosis, the slit lamp project a beam of light into the patient’s eye through a control diaphragm.

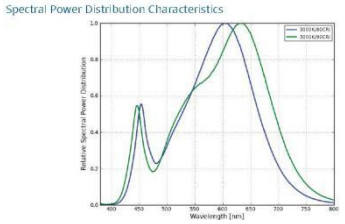
The Slit Lamp LS-1A,LS-1B has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicates.

Comparation Table

Descriprtive information	**Proposed Device**	**Predicate Device**	**Description of differences and discussion**
Manufacturer	Chongqing Sunkingdom Medical Instrument Co.,Ltd	66 Vision Tech Co.,Ltd.	
510(k)Number		K131711	
Proprietary or Model Name	LS-1A,LS-1B Portable Slit Lamp microscope	YZ3 Portable Slit Lamp microscope	
Indications for Use	The Sunkingdom Portable Slit lamp is an AC-powerslit lamp 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.	Same	
Flammability of materials near the light source	None	None	

Descriptive information	**Proposed Device**	**Predicate Device**	**Description of differences and discussion**
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≥250000Lx	Maximal Illumination≥30000Lx	The brightness controls are by a variable continuous potentiometer. It allow the user to select a convenient brightness to achieve optimum results. The maximum brightness is significantly different. The predicate device YZ3 has a maximumbrightness ≥30000LUX, the LS-1A and LS-1B has a maximum brightness of 250000LUX. For light hazard, test according to ISO 15004-2 is proceed, LS-1A and LS-1B are classified into Group 2 intruments. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 83 seconds. Manufacturer will indicate this caution on label to remind the practice. LS-1A and LS-1B are conform to the relevant electronic and optical safety standard of ANSI AAMI IEC60601-1-2, AAMIES60601-1:2005, ISO 15004-2, and ISO10939. It's approved to be safe, and no issues of safety and effectiveness.

Descriprtive information	Proposed Device	Predicate Device	Description of differences and discussion
Slit Width	0.1mm,0.2mm,0.8mm, 1mm, 5mm, 12mm	0 to 12mm continuously adjustable	LS-1A & LS-1B from SK have 6 step of the slit width, the maximum slit width is 12mm which is same like predict device of 66 vision, all other step which is in the width area of 66 vision. The differences are not significant, There are no new issues of safety and effectiveness.
Slit Length	1mm,5mm,8mm,12mm	0.2mm,1mm,2mm,12mm	The differences are not significant. As the illumination field is defined by a circular aperture, the slit length cannot be larger than the slit width. The maximum slit length of SK MED is also the same as predict device which is 12mm. There are no new issues of safety and effectiveness.
Radial movement of the slit light illumination relative to the microscope axis	Horizontal±60 °	Horizontal ±30 °	The predicate device has horizontal±30 °.Whereas,the LS-1A,LS-1B slit lamp has horizontal±60. When examing the conea, the proposed device have larger angle to ensure the clear view of conea formed. SK MED's parameter is better than the predicate device. There are no new issues of safety and effectiveness.
Stereo angle	13 º	Same	The differences are not significant There are no new issues of safety and effectiveness.

Descriprtive information	**Proposed Device**	**Predicate Device**	**Description of differences and discussion**
Light sources	LED	LED	LED is a safety light source, it already filter the IR and UV light which is harmful to eye.  Both SK MED and predicate device are using LED light source. The differences are not significant , There are no new issues of safety and effectiveness.
Pupil-distance	49-75mm	50 to 75mm	The differences are not significant, There are no new issues of safety and effectiveness.
Eye piece	12.5X	10X,16X	The differences are not significant, There are no new issues of safety and effectiveness.
Objective	1X	Same	There are no new issues of safety and effectiveness.
Total magnifications	LS-1A:10X LS-1B:10X,16X	10X,16X(Optional)	The differences are not significant.There are no new issues of safety and effectiveness.
Filter	Neutral density, red-free, cobalt blue	Cobalt blue, Red-free, Color Temperature Compensation	The differences are not significant. There are no new issues of safety and effectiveness.

Descriprtive information	Proposed Device	Predicate Device	Description of differences and discussion
Optical Radiation Emissions	Conform to ISO 15004-2	Conform to ISO 15004-2	The predict device and LS-1A & LS-1B are all conform toISO15004-2. The differences are not significant. There are no new issues of safety and effectiveness.
Working distance	100mm(10X), 80mm(16X)	60mm	The differences are not significant. There are no new issues of safety and effectiveness.
Power	7.4V/680mAh,AA Battery	7.4V 2200mA Li Battery, Rechargeable	The differences are not significant. Predicate device has 7.4V 2200mA Li Battery, whereas the slit lamp LS-1A,LS-1B has 7.4V/680mAh,AA Battery. As all slit lamps conform to the relevant standard ISO 10939. There are no new issues of safety and effectiveness.
Working time	4 hours	2.5 hours	The proposed device working longer than predicate device which is a better performance. The differences are not significant. There are no new issues of safety and effectiveness.
Net Weight	890g(with battery)	900g	There are no new issues of safety and effectiveness.

Difference between each model

Model / Magnification		LS-1B	LS-1A
Microscope Type	Type	Binocular Convergence Biomicroscope	
	Eyepiece	13°	
	Magnification	10X，16X	10X
	Work distance	16X:80mm,10X:100mm	10X:100mm
	Pupil distance	49mm~75mm	
	Diopter	-7D~+7D	
Illumination System	Slit width	0.1mm,0.2mm,0.8mm,1mm, 5mm ,12mm	
	Slit length	1mm,5mm,8mm,12mm	
	Slit angle	Horizontal ±60°	
	Filters	Neutral density,Redfree(green),Cobalt blue	
	Light source	LED	
	Brightness	≥250000Lux	
Power Supply	LED work voltage	DC7.4V,680mAh	
	Battery	7.4V/680mAh,AA Battery	
Slit lamp LS-1A,LS-1B are equivalent to each other, the devices all have the same indications for use and the devices are equivalent to the predicate devices.			

Performance Data

The following perfomance data were provided in support of the substantial quivalencedetermination.

Biocompatibilitytesting

The biocompatibility evaluation for the Sunkingdom Slit Lamp LS-1A,LS-1B wasconductedinaccordancewiththe21CFR58GoodLaboratoryPracticefor Nonclinical Laboratory Studies,ISO 10993-10:2010 ”Biological Evaluation of Medical Devices-Part 10:Tests For Irritation And Skin Sensitization”,Jul,26,2016,and Standard ISO 10993-5:2009 “Biological Evaluation of Medical Devices-Part 5:Tests For In Vitro Cytotoxicity”,Dec,23,2016,as recognized by FDA.The portable slit lamp of testing included the followingtests:

- VitroCytotoxicity
- SkinIrritation
- SkinSensitization

The test article Chinrest pat and Forhead band extract did not show potential toxicitytoL-929cells.TheextractofappliedsampleChinrestpatandForehead banddidnotinduceskinirritationinrabbitskin.ChinrestpatandForheadband extract showed no significant evidence of causing skin sensitization in the guineapig.

The material of forhead rest bracket of Portable Slit Lamp LS-1A/LS-1B which is in contact with patient is the same material as the material of test report.

Electrical safety and electromagnetic compatibility(EMC)

Electrical safety and EMC testing were conducted on the Sunkingdom Slit Lamp LS-1A, LS-1B. The system complies with the "ANSI AAMI IEC60601-1-2:2007/(R)2012,Jun,27,2016, standard for EMC and the ANSI AAMIES60601-1:2005/(R)2012AndA1:2012,Jul,09,2014,standardforsafety.

Performance testing

The performance testing was conducted on the Sunkingdom Slit Lamp LS-1A,LS-1B, consisting of the optical body, movement mechanism, illumination system and portable handle. The system complies with Standard ISO 10939 "Ophthalmic instruments-Slit-Lamp microscopes",Dec,19,2017, in accordance with Slit lamp guidance - VI References.

Light Hazard Protection

The light hazard protection for Ophthalmic Instruments was conducted on the Sunkingdom Slit Lamp LS-1A, LS-1B. The system complies with the ISO 15004-2:2007 Ophthalmic instruments -- Fundamental requirements and test methods -- Part 2: Light hazard protection .

It is classified into Group 2 instruments according to the requirement of ISO 15004-2, The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 83 seconds.

Conclusions

In accordance to 21 CFR 807.92(d) and based on the technical characteristics and the results of the performance tests we conclude that Portable slit lamp LS-1A,LS-1B are substantially equivalent and as safe and effective as the predicate device 66 Vision Tech Co.,Ltd YZ3 Portable Slit Lamp.