DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 16, 2017

Chongqing Yeasn Science-Technology Co., Ltd.
% Ms. Iris Fung
Official Correspondent
SGS-CTSC Standards Technical Services Co., Ltd.
198 Kezhu Road, Scientech Park Guangzhou Economic &
Technology Development District
Guangzhou, CN Guangdong

Re: K161764
Trade/Device Name: Slit Lamp, Model: YF-100
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: December 3, 2016
Received: January 3, 2017

Dear Ms. Fung:

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,

Denise L. Hampton -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)*
K161764

Device Name
SLIT LAMP

Indications for Use *(Describe)*
The SLIT LAMP is an AC-powered slit lamp biomicroscope that is intended for use in examining the anterior eye segment, from the corneal 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 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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510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

Date of the summary prepared: February 10, 2017

1. Submitted Information

- 510(k) Owner's Name: CHONGQING YEASN SCIENCE–TECHNOLOGY CO., LTD
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- Phone:（86 23）62797666-8050
- Fax:（86 23）62766200
- Contact Person: Bing Hu/Managing Director
- Email: tech@yeasn.com

2. Application Correspondent:

- Company Name: SGS-CSTC Standards Technical Services Co., Ltd.
- Address: 198 KEZHU Road, SCIENTECH Park Guangzhou Economic & Technology Development District, Guangzhou, Guangdong, CHINA
- Contact Person: Ms. Iris Fung
- Tel: +86-20-32136908
- Email: Iris.Fung@sgs.com

3. Subject Device Information

- Trade Name: SLIT LAMP, Model: YF-100
- Common Name: Slit Lamp
- Classification name: AC Powered Slit Lamp Bio-microscope
- Review Panel: Ophthalmic
- Product Code: HJO

- Regulation Class: II
- Regulation Number: 21 886.1850

4. Predicate Device Information

Sponsor	APPASAMY ASSOCIATES
Device Name	APPASAMY SLIT LAMP, model:A1A-11 AND A1A-12 SERIES
510(k) Number	K082031
Product Code	HJO
Regulation Number	21 886.1850
Regulation Class	2

5. Device Description

The slit lamp is an instrument consisting of a high-intensity light source that can be focus to shine a thin sheet of light into the eye. The binocular slit-lamp examination provides a stereoscopic magnified view of the eye structure in detail, enabling diagnosis of diseases or trauma, which affect the structural properties of the anterior segment of the eye.
The device consists of a base plate, chin rest, fixation light, illumination light, slit project, focusing ring and other accessories that in aid of examination. The patients can rest their chin and forehead on a support to keep the head steady.
It is powered by the specified adapter (model: MDS-060BAS12A) which is certificated by ANSI/AAMI ES 60601-1 and considered as part of this equipment. Appliance coupled with US Plug.

6. Intended Use / Indications for Use

The SLIT LAMP is an AC-powered slit lamp biomicroscope that is intended for use in examining the anterior eye segment, from the corneal 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 segment of the eye.

7. Test Summary for SLIT LAMP

YF-100 has been evaluated the safety and performance by lab bench testing as following:

- The YF-100 was evaluated to IEC 60601-1:2005 (3rd edition) for electrical safety, and passed.
- The YF-100 was evaluated to IEC 60601-1-2 for EMC compliance, and passed at Class A radiated emissions limits.
- The YF-100 was evaluated to ISO 15004-1 for environmental tolerance of ophthalmic devices and passed.
- The YF-100 was evaluated to ISO 15004-2 for assessment of photo-biological safety of light intensity limits, and passed.
- The YF-100 was evaluated to ISO 10939, which requires assessment to ISO 15004-1, 15004-2, and IEC 60601-1, and passed.

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of SLIT LAMP is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Remark
Basic Unit Characteristics			
Device Name and Model	SLIT LAMP, Model: YF-100	APPASAMY SLIT LAMP, model:A1A-11 AND A1A-12 SERIES	--

Elements of Comparison	Subject Device	Predicate Device	Remark
510 (K) Number	K161764	K082031	--
Intended Use	The SLIT LAMP 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.	Slit Lamp is an AC-powered slit 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 segments.	SE
Microscope type	Galileo binocular converging	Galilean type	SE
Exposure parameters	1. Magnification Change: Continuous by manual zoom 2. Eyepieces:12.5× 3. PD Range:55mm to 80mm 4. Slit Width:0mm to 14mm continuous（become a circle at 14mm） 5. Slit Apertures:φ0.3mm、φ5.5mm、φ9mm、φ14mm 6. Slit Angles: 0° to 180° continuous adjustable from vertical to horizontal direction 7. Diopter adjustment:－5.00D to +5.00D 8. Working Distance: 100mm 9. Longitudinal(In/Out）: Movement 100mm 10. Lateral(Left/Right）:	1. Magnification Change: Continuous by manual zoom 2. Eyepiece: 12.5x 3. PD Range: 55mm to 75mm 4. Slit Width: 0mm to 14mm 5. Slit Apertures: 0mm to 14mm, φ0.2, φ1, φ3, φ4, φ6, φ10, φ14mm 6. Slit Angles: 0° to 180° 7. Diopter adjustment: -6D to +6D 8.Working Distance: 100mm 9. Longitudinal(In/Out）: Movement 99mm 10. Lateral(Left/Right）: Movement 118mm 11. Vertical(Up/Down）: Movement 30mm 12. Chin Rest vertical:55mm	Note 1

Elements of Comparison	Subject Device	Predicate Device	Remark
	Movement 100mm 11.Vertical(Up/Down）: Movement 30mm 12. Horizontal: Movement 10mm 13.Chin Rest Elevation : 70mm		
Filters	Heat aborption, redfree, cobalt blue	Heat absorbing, Green, Cobalt Blue	SE Note 1
Total Magnification	6.4×,10×,16×,25×,40×	5.5x to 35.0x	SE Note 1
Fixation Light	Red LED（620nm～720nm）	LED	SE Note 1
Data collection and/or display system	N/A	N/A	SE
Flammability of materials	This instrument is not suitable for use in a flammable atmosphere. Do not use this instrument if any flammable gases are present.	This instrument is not suitable for use in a flammable atmosphere. Do not use this instrument if any flammable gases are present.	SE
Max. temperature of parts of the device held by the operator or accessible to the patient	No parts of device with patient/operator contact is energized and remains at ambient temperature.	No parts of device with patient/operator contact is energized and remains at ambient temperature.	SE
Brightness Control	3V LED lamp	12V 30W halogen bulb	SE Note 1
Additional Features			
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	SE
Compliance with	IEC 60601-1-2	IEC 60601-1	--

Elements of Comparison	Subject Device	Predicate Device	Remark
Safety Standards	IEC 60601-1:2005 ISO 15004-1 ISO 15004-2 ISO 10939	ISO 10939:2007 ISO 15004-2:2007	
Input Voltage AC	230 / 110V - 50 / 60 Hz	230 / 110V - 50 / 60 Hz	SE
Power Rating	60W	45W	SE Note1

Note 1:

Although the Brightness Control, Power Rating, Filters, Total Magnification and Fixation Light of subject device are a little different from the predicate devices, they are all compliant with requirements of IEC 60601-1, ISO 15004-2, ISO 10939 and Guidance for Slit Lamp. So the differences of the function specifications will not raise any safety or effectiveness issue.

Finial Conclusion:

The subject device “SLIT LAMP” is Substantially Equivalent to the predicate device.