



Food and Drug Administration
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June 22, 2016

Shanghai Bolan Optical-Electric Co., Ltd.
Mr. Johnny Hu
Manager
No.29, Jiuyuan Road
Qingpu Industrial Park
Shanghai, China
201700

Re: K153545

Trade/Device Name: BL-5000 Portable Slit Lamp
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: May 15, 2016
Received: May 17, 2016

Dear Mr. Hu:

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

Indications for Use

510(k) Number (if known)

Device Name

BL-5000 portable slit lamp

Indications for Use (Describe)

The BL-5000 portable 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.

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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

1. **Date Prepared [21 CFR 807.92(a)(1)]**

December 1st 2015

2. **Submitter;s Information [21 CFR 807.92(a)(1)]**

Company Name: Shanghai Bolan Optical-Electric Co., Ltd.
Company Address: No. 29, Jiuyuan Road, Qingpu Industrial Park,
Shanghai, China 201700
Fax: +86-21-69225166
Email: sales@sh-bolan.com

3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name: BL-5000 Portable Slit Lamp
Common Name: Portable Slit Lamp
Product Code: HJO
Regulation Number: 21 CFR 886.1850
Device Class: Class II

4. **Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]**

The identification of predicates within this submission is as follow:

Predicate I

Manufacturer: REICHERT, INC.
Trade Name: PSL Portable Slit Lamp
Product Code: HJO
Classification Name: AC-Powered Slitlamp Biomicroscope
Regulation Number : 886.1850
FDA 510 (k) #: K061330

5. **Description of the Device [21 CFR 807.92(a)(4)]**

The BL-5000 portable slit lamp 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 BL-5000 portable slit lamp is composed of the following components: microscope unit, illumination unit, base unit 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.

6. Indications For Use [21 CFR 807.92(a)(5)]

The BL-5000 portable 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. Technological Characteristic [21 CFR 807.92(a)(6)]

The BL-5000 Portable Slit Lamp has similar technological characteristics to the predicate devices. The BL-5000 Portable Slit Lamp and the predicate devices are all AC powered slit lamp biomicroscopes that project a beam of light into the patient's eye through a control diaphragm. Exposure parameters including slit image width, slit image length, illumination field diameter and slit direction are the same or similar to the specifications of the previously cleared predicate devices. All controls are manual. Neither the BL-5000 nor its predicate device has data collection, display systems, motors, or software.

The BL-5000 Portable Slit Lamp uses the warm white LED as the light source, the exposure condition is continuous wave.

Light source operation characteristics:

Wavelength: 380nm-780nm

Maximum output: 16.77mW

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Non-clinical consideration:

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

IEC 60601-1:2006+A1:2012 medical electrical equipment -- part 1: general requirements for basic safety and essential performance

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.

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

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 which is non-hazardous.

ISO 10939:2007 Ophthalmic Instruments – Slit-lamp microscopes found that the BL-5000 complies with the requirements of the standard.

Also the comparison table below demonstrates that the proposed device BL-5000 is substantial equivalence to the predicated device.

Comparison Item	Proposed Device	Predicate Device PSL Portable Slit Lamp (K061330)
Indications For Use	The BL-5000 portable 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	intended for use in eye examination of - the anterior 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.
Method of Operation	Handheld	Handheld
Data Collection/ Display System	None	None
Maximum Temperature	None	None
Total magnifications:	10X, 16X;	10X, 16X;
Diopter adjustment	± 5D	± 7D
Filter	Green, cobalt blue, Color temperature conversion	Green, cobalt blue, Color temperature conversion
Slit rotation	± 30°C	± 30°C
Light source	High luminance white LED	High luminance white LED

Slit width	0~12.5mm	0~11mm
Slit length	0~12.5mm	0~11mm
Light source	White LED	White LED

The BL-5000 Portable Slit Lamp has the same intended use and principles of operation, most technological characteristics are same or similar as the previously cleared predicates.

9. Conclusion [21 CFR 807.92(b)(3)]

BL-5000 Portable Slit Lamp is substantially equivalent to the currently legally marketed devices. It does not introduce new indications for use, have the same technological characteristics and do not introduce new potential hazards or safety risks.