K131589

Keeler

Ophthalmic Instruments

3. 510(k) Summary

JUN 2 7 2013

3.1 Submitter's information

The submitter of this pre-market notification is:

Mr. Nickie Power (Quality Manager).

Keeler limited

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Contact Person: Mr. Nickie Power

Date summary prepared: January 14, 2013

3.2 Device Identification

Device Trade Name:	Keeler Slit Lamp - H Series
Common Name:	AC Powered Slit lamp Biomicroscope
Class:	II
Classification Panel:	86
Product Code:	HJO
Regulation Number:	886.1850

3.3 Predicate Device

Predicate Device:	Slit Lamp BQ 900
510(k) No:	K100202
Manufacturer:	Haag-Streit AG
Common Name:	AC Powered Slit lamp Biomicroscope
Class:	II
Classification Panel:	86
Product Code:	HJO
Regulation Number:	886.1850

3.4 Device description

An AC-powered slit lamp biomicroscope is an AC-powered device that is a microscope intended for use in eye examination that projects into the patient's eye through a control diaphragm a thin, intense beam of light.

This Keeler Slit Lamp has an XYZ translation base that is either mounted onto a custom table top supplied by Keeler or can be mounted on a third parties table top (refraction unit) by suitably trained technicians.

Fitted to the XYZ base is the illumination and observation system; fitted to the table top is the chinrest assembly with fixation target.

The illumination system rotates around its mounting axis and has a number of filters and graticules allowing the user to control precisely the characteristics of the examination light.

The magnification body has a magnification change systems and eyepieces adjustable for the user's individual pupillary distance and distance correction.

The patient is seated in front of the slit lamp with his/her chin in the chin rest and forehead against the forehead rest. The chin rest can be adjusted in height to align the eyes of the patient with the optics/light beam.

With the control lever the instrument can be moved back and forward until the slit appears in focus on the cornea. The image can be observed through the microscope. The base unit has a rheostat to control the illumination level.

Various magnifications can be selected on the microscope. For different observations the slit width can be changed, the slit can be tilted horizontally and vertically, and the angle between the illumination unit and the microscope can also be varied horizontally.

3.5 Indications for Use

The Keeler Slit Lamp is an AC-powered Slit lamp biomicroscope and 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

This device is intended to be used only by suitably trained and authorised healthcare professionals.

3.6 Comparison of the device with the Predicate

The Haag-Streit BQ900 has been chosen as the substantially equivalent device, it has the same intended use and classification.

The Keeler Slit Lamp has the following similarities to those of the predicate device:

-has the same indication for use,

-uses the same operating principle,

-incorporates the same basic optical design.

Refer to the table below for comparison between Keeler and Haag Streit BQ 900 Slit Lamps (K100202).

Device	Predicate Device ***Predicate Device Haag-Streit Slit Lamp BQ 900***	Keeler Slit Lamp H- Series	Discussion
Intended use	An ac-Powered slit lamp biomicroscope is an AC-powered device that is a microscope intended for use in eye examination that projects into the patient's eye through a control diaphragm a thin, intense beam of light	An ac-Powered slit lamp biomicroscope is an AC-powered device that is a microscope intended for use in eye examination that projects into the patient's eye through a control diaphragm a thin, intense beam of light	Same
Microscope	Galilean converging binoculars	Galilean converging binoculars	Same
Type	AC Powered Biomicroscope Slit Lamp	AC Powered Biomicroscope Slit Lamp	Same
Angle of Convergence	13°	13°	Same
Magnification	6.3x / 10x / 16x / 25x / 40x	x6, x10, x16, x25 & x40	The difference are not significant and does not affect the safety or effectiveness of the device
Objective lens working distance	105mm	107mm	The difference are not significant and does not affect the safety or effectiveness of the device
Field of view	32.0 @ 6.3x / 20.0 @ 10x / 12.7@ 16x / 8.0@ 25x / 5.1@ 40x	34.0 @ 6x / 22.0 @ 10x / 14 @ 16x / 8.5 @ 25x / 5.5 @ 40x	The difference are not significant and does not affect the safety or effectiveness of the device

Range of PD adjustment	52 - 78 mm	49.0 to 77mm	There is a difference in the range of adjustment however this does not affect safe or effectiveness on the devices as both conform to the requirement of ISO 10939
Eyepiece dioptric adjustment range	+ 8 to - 8 diopters	+ 8 to - 8 diopters	same
Slit Projection Unit			
Slit Length	1– 8 mm continuous	12mm (1mm – 12mm continuously variable)	The difference is not significant An Iris usually has a diameter of 6mm max, therefore a slit length of 12mm is more than sufficient, meeting the requirement specified in ISO 10939 and does not affect the safety or effectiveness of the device
Slit Width	0 – 8 mm continuous	0-12mm continuously variable	The difference is not significant; this does not affect safety or effectiveness of the devices as both conform to the requirement of ISO 10939. Slit lamps are used to examine the inner part of the eye and usually a narrow slit of less than 1mm is needed. For this reason the maximum slit width is not critical as long as it is ≥ 8mm
Light source	7.5V, 38 W Halogen Lamp 24VDC 1A LED	6V 20W Halogen lamp and LED - As the slit lamp conform to the relevant standard ISO 10939, there are no issues of safety and effectiveness.	There is a difference in light sources used however all light sources must conform to the requirements of 15004-2 Photo-toxicity therefore there is no affect on safety or effectiveness
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	Same

Light intensity selection	Three selections: Full, 1/4 and 1/16 via neutral density filter.	0-100% continuous potentiometer	The difference is not significant as they allow the user to select the necessary light intensity to perform the relevant task
Filter	Blue, red free (green), grey (10%) The UV filter and the heat absorption filter are permanently mounted	Clear; red free; neutral density; diffuser; blue; IR heat absorbing filter permanently installed	The difference is not significant and does not affect safety or effectiveness, both devices have a permanently installed heat absorbing filter
Electrical ratings			
Input voltage	AC 100-240 V, 50/60Hz	AC 100-240 V, 50/60Hz	Same
Power output	30VA	30VA	Same
Output Voltage	12 V DC	12 V DC	Same
Compliance with Safety standards	IEC60601-1-2 IEC60601-1 ISO 15004-2	IEC 60601-1-2 IEC 60601-1 ISO15004-2	Same

3.7 Summary of Performance, EMC and Safety Testing

The Keeler Slit Lamp (H – Series) was evaluated against the requirements of BS EN ISO 15004-2 and BS EN ISO 10939 for radiation hazards, to IEC 60601-1 for electrical safety and to IEC 60601-1-2 for electromagnetic compatibility.

In all tests the slit lamp was in compliance with these FDA recognized standards.

3.8 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this Premarket Notification, Keeler limited concludes that the H- Series Slit Lamp is safe and effective, and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

Keeler Limited
% Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K131589
Trade/Device Name: Keeler Slit Lamp – H Series
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slit Lamp
Regulatory Class: Class II
Product Code: HJO
Dated: June 4, 2013
Received: June 13, 2013

Dear Mr. Rongero:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 Y. Alexander -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

Keeler

Ophthalmic Instruments

2. Indications for Use Form

510(k) Number (if known):

Device Name: Keeler Slit Lamp H-Series.

Indications for Use:

The Keeler Slit Lamp is an AC-powered Slit lamp biomicroscope and 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

This device is intended to be used only by suitably trained and authorised healthcare professionals.

Prescription Use _√_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew Yang -S
2013.06.27
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Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K131589