

510(k) Summary of Safety and Effectiveness (K140451)

1. Submitter's Information

The submitter of this special pre-market notification is:

Name: Mr. Neil Atkins (Engineering Manager).
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Contact Person: Mr. Neil Atkins
Date summary prepared: 19th February, 2014 (Revised 10th April 2014)

2. Device Identification

Device Trade Name: Keeler Slit Lamp H-Series Digital
Regulation Number: 21 CFR 886.1850
Regulation Name: AC Powered Slit lamp Bio-microscope
Regulation Class: II
Product Code: HJO, HKI

3. Predicate Device

For the digital version of slit lamp biomicroscope instrument, the predicate cited is the Keeler non-digital version of the same instrument:

Device Trade Name: Keeler Slit Lamp H- Series
510(k) Number: K131589
Common Name: AC Powered Slit lamp Bio-microscope
Class: II
Classification Panel: 86
Product Code: HJO
Regulation Number: 886.1850

For the additional USB digital camera module fitted to the Keeler Slit Lamp H-Series Digital instrument by the user for image capture, the predicate cited, which offers the same digital camera option in the US market, is:

Device Trade Name: Slit Lamp BQ900 (with IM900 Imaging Module Option)
Manufacturer: Haag Streit AG
510(k) Number: K100202
Common Name: AC Powered Slit lamp Bio-microscope
Class: II
Classification Panel: 86
Product Code: HJO
Regulation Number: 886.1850

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4. Device Description

The Keeler Slit Lamp H-Series device is AC-powered slit lamp bio-microscope intended for use in eye examination that projects into the patient's eye through a control diaphragm a thin, intense beam of light. It is mounted on an XYZ translation base that is either mounted onto a custom table top supplied by Keeler or can be mounted on a third party's 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 patient is seated in front of the slit lamp with his/her chin in the adjustable chin rest and forehead against the forehead rest. 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 digital option for the H-Series Slit Lamp enables digital photographs to be taken to capture the image being observed, for further viewing and record purposes. It comprises an additional USB camera module that can be fitted by the user between the binocular eyepiece assembly and the main body of the microscope, which is connected to a powered USB3 hub enclosed within the microscope base, for onward connection to a medically approved PC.

Addition of this option necessitates modifications to the illumination tower to provide background lighting via a fibre optic light tube when capturing digital images.

There are two variants of the H-Series Digital Slit lamp. The first variant uses an incandescent light source, which is used to illuminate the eye during examination and provide background illumination to aid digital photography.

The bulb is more powerful than the bulb sited in the predicate 510(k) [K131589] due to the requirement for additional background illumination for digital photography. The quantity of light for illuminating the eye is comparable to the product sited in K131589, and therefore poses no additional risk to the safety and effectiveness of the product.

The second product variant is an LED illumination option, which again provides light to illuminate the eye during examination and provides background illumination for digital photography. Both variants are factory fitted and comply with ISO 15004-2:2007.

5. Indications for Use

The following indications for use for the Keeler Slit Lamp H-Series remain unchanged by addition of the digital photography option:

"The Keeler Slit Lamp is an AC-powered Slit lamp bio-microscope 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 authorized healthcare professionals "

6. Comparison with Cleared Device

The Keeler Slit Lamp has been modified to accommodate an additional USB digital camera module, which is connected to a USB hub in the microscope base, for onward connection to a

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standard PC for displaying the captured images.

These hardware additions have necessitated additions or changes to the product labeling on the previously cleared device [K131589], some of which are associated with the higher-powered halogen bulb option. Details of the significant differences are shown in the following substantial equivalence table comparing the cleared Keeler non-digital and modified digital devices:

Feature	H-Series Slit Lamp [K131589]	H-Series Slit Lamp Digital	Discussion
Intended use	As stated	As stated	No change
Bio-microscope components			
Bio-microscope	Galilean converging binoculars with detachable eyepiece head	Galilean converging binoculars with detachable eyepiece head	As head can be separated from the body, intervention of module does not change these elements
Digital Camera Module	Not fitted	Optional fitment	Fitted by user when required, or supplied fitted for customers
Image Capture Button	Not fitted	Fitted to joystick	Required for digital facility
Camera Exposure Buttons	Not fitted	Adjacent to joystick for camera aperture adjustment	Required for digital facility
USB3 Hub (Internal)	Not fitted	Fitted in XYZ base	Required for digital facility
Slit Lamp Illumination Options	6VDC 20W halogen bulb	12VDC 30W halogen bulb	Required for slit lamp illumination with some light used for background lighting
	LED	LED (first)	Required for slit lamp illumination
Background Illumination Adjuster	Not fitted	Fitted to top of illumination tower	Allows adjustment for optimum lighting for digital photography
Background Light Source Options	Not fitted	12VDC 30W halogen bulb as above	Required for higher background light output but still conforms to requirements of 15004-2 Phototoxicity with slightly longer exposure time
	Not fitted	LED (second)	Required for background lighting
Background lighting duty cycle – halogen bulb option only	Not applicable	Limited to 6 minutes for 50% duty cycle at maximum brightness	Ensures body of light source does not exceed 62.3°C limit demanded by IEC 60601-1 compliance
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	As a result of phototoxicity testing to ISO 15004-2 maximum exposure increased from 13 to 17 minutes for bulb option (LED maximum exposure is unchanged at 12.5 minutes)
Electrical ratings			
Input voltage	AC 100-240 V, 50/60Hz	AC 100-240 V, 50/60Hz	Same
Power output	30VA	52VA (2.2A)	Required for change to 12V bulb

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Feature	H-Series Slit Lamp [K131589]	H-Series Slit Lamp Digital	Discussion
Output Voltage (bulb option)	12 V DC	24 V DC	Required for change to 12V bulb
Output Voltage (LED option)	12 V DC	12 V DC	No change to PSU required
Compliance with Safety Standards	IEC60601-1 IEC60601-1-2 ISO 15004-1 ISO 15004-2 ISO 10939	IEC60601-1 IEC60601-1-2 ISO 15004-1 ISO 15004-2 ISO 10939	Same

A further substantial equivalence comparison has been made between the USB digital camera modules offered as options by Keeler and Haag Streit for their digital slit lamps:

Feature	Haag Streit IM 900 Camera Option	Keeler DSL Digital Camera Option	Comment
Digital Camera Module			
Stated Intended Use	Digital photography and video for documentation of eye	Digital photography and video for documentation of eye	Same
Mounting Methods	CM01 module mounted between eyepiece assembly and magnification block, utilizing same locking ring securing method	Keeler module mounted between eyepiece assembly and magnification block utilizing same screw knob/pin securing method	Essentially same mounting mechanism with insignificant differences between securing methods
Beam Splitter Control	Two position control on side of module to allow 100% of light to reach observer or 30% to observer and 70% to camera	30% to observer and 70% to camera all the time	Camera function is permanently enabled at the same level.
Aperture Control	6-position control on side of module	Aperture fixed at maximum	Image quality maximised
Power Supply	Supplied from separate supply unit via control module	Supplied from isolated medical PC USB port	Essentially same
Digital Camera Specifications			
Beam Path	Right Side	Left Side (see note below)	A camera can be mounted on either eyepiece. Manufacturing preference. No impact on effectiveness.
Camera Model	Sony ICX274	Sony ICX274	Same
Sensor Technology	CCD	CCD	Same
Resolution	1600x1200 pixels	1600x1200 pixels	Same
Sensor Dimensions	1/1.8" (7.04x5.28mm)	1/1.8" (7.04x5.28mm)	Same
Frame Rate	12 fps (frames per second)	12 fps (frames per second)	Same

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Feature	Haag Streit IM 900 Camera Option	Keeler DSL Digital Camera Option	Comment
LED Red/Green Indicators	USB status	USB status	Same
Camera Control Module			
Construction	Retrofittable RM01 module mountable on bio-microscope XYZ table, with exposure controls and trigger bar, secured to base by magnets	Additional USB hub and associated capture button on joystick and exposure control buttons on base cover, pre-installed on digital version of slit lamp	Keeler features are built in predicate device uses retro-fit modules. Essentially same.
Cable Connections	Between camera module and control module, and control module and PC	Between camera module and control module, and control module and PC	Same
Exposure Adjustments	2 sets of 2 buttons providing a range of settings on trigger module cover	1 set of 2 buttons providing a range of settings on trigger module cover	Essentially same function
Exposure Trigger	Trigger bar at front of trigger module	Capture button incorporated into top of joystick	Essentially same function
Standards Compliance	IEC 60601-1 (Class 1 Type B) and IEC 60601-1-2	IEC 60601-1 (Class II Type BF) and IEC 60601-1-2	Essentially same
Background Illumination			
Construction	Alternative (background illumination ready) lamp head for illumination tower provides light output for fibre optic connection to illumination area	Custom designed lamp cover provides light output for fibre optic connection to illumination area	Essentially same function
Illumination Control	Variable rheostat on XYZ translation base	Variable rheostat on XYZ translation base	Essentially same
Auxiliary Diffuser and Blue Filter	Provided	Provided	Same
Computer Specifications			
Electrical Safety	Requires conformity with IEC 60601-1 or operated with transformer to isolate PC from mains	Requires conformity with IEC 60601-1 or operated with transformer to isolate PC from mains	Same
Performance Specification	Intel Pentium 5 or better, 2GHz or higher, with at least 3GB RAM and Windows OS	Intel Core i5, 2 GHz or higher, with at least 4GB RAM and Windows OS	Essentially same

Display of images captured by the camera module requires use of FDA cleared image display software on the medically approved PC, which is stand-alone and hence not included in this submission.

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7. 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 conclude that the modified version of the H-Series Slit Lamp with the digital capture option is safe and effective, and substantially equivalent to the unmodified version of this device used as a predicate.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - W066-G609
Silver Spring, MD 20993-0002

July 11, 2014

Mr. Eugene R. VanArsdale
Marketing Manager
c/o Keeler Instruments Inc.
456 Parkway
Broomall, PA 19008-4295

Re: K140451

Trade/Device Name: Keeler Slit Lamp H-Series Digital
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: HJO, HKI
Dated: April 11, 2014
Received: April 14, 2014

Dear Mr. VanArsdale:

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 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

Indications for Use

510(k) Number (if known)
K140451

Device Name
Keeler Slit Lamp H-Series Digital

Indications for Use (Describe)

The Keeler Slit Lamp is an AC-powered slit lamp bio-microscope 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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