DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 10, 2015

Keeler Limited
Ms. Irina Proutski
Head of Regulatory And Quality Affairs
Clewer Hill Road
Windsor, Berkshire
GB SL4 4AA
United Kingdom

Re: K151394
Trade/Device Name: Keeler Slit Lamp Z-series and Keeler Slit Lamp Z-series Digital
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: August 7, 2015
Received: August 10, 2015

Dear Ms. Proutski:

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

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)*
K151394

Device Name
Keeler Slit Lamp Z-series and Keeler Slit Lamp Z-series Digital

Indications for Use *(Describe)*
The Keeler Slit Lamp Z-series and Keeler Slit Lamp Z-series Digital are AC-powered Slit lamp bio-microscopes 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

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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Keeler
Ophthalmic Instruments

510(k) Summary of Safety and Effectiveness

1.1 Submitter's Information

The submitter of this special pre-market notification is:

Name:	Dr. Irina Proutski (Head of Regulatory and Quality Affairs).
Address:	Keeler Limited, Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK
Company Phone No:	+44 (0) 1753 827125
Company Fax No:	+44 (0) 1753 827145
Contact Person:	Dr Irina Proutski
Date summary prepared:	17th April 2015

1.2 Device Identification (Unmodified)

Device Trade Name:	Keeler Slit Lamp - H Series and Keeler Slit Lamp H-series Digital (FDA approval letters K131589 and K140451)
Common Name:	AC Powered Slit lamp Bio-microscope
Class:	II
Classification Panel:	86
Product Code:	HJO
Regulation Number:	886.1850

1.3 Device Description

1.3.1 Unmodified Device

There are two cleared unmodified devices used as predicate for the purpose of this registration: The Keeler Slit Lamp H-Series device and its digital variant. Both are AC-powered slit lamp bio-microscopes intended for use in eye examination that projects a thin intense beam of light into the patient's eye through a control diaphragm. 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 bio-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 bio-microscope, which is connected to a powered USB3 hub enclosed within the bio-microscope base, for onward connection to a medically approved PC. To accommodate addition of this option the illumination tower has been modified 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 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.

1.3.2 Modified Device

The Keeler Slit Lamp Z-series (modified device) exists in two variants: non-digital and digital. The Z-series variant of the product is introduced as a lower cost alternative of the H-series to meet expectations of the optometry market. The Keeler Slit Lamp Z-series includes bottom-illuminating tower assembly instead of top-illuminating Haag-type illuminating tower. The high percentage of components/assemblies used on cleared Keeler Slit Lamp H-series (unmodified device) will be utilized on the Z-series slit lamp.
The modified device will come in a few different configurations assembled from the same components (022_Configurations of the Modified Device). High percentage of components shared between H-series and Z-series slit lamps are used on the cleared H-series device.
Similar to the H-series slit lamp, the Z-series will offer a digital option for recording and storing images and a range of magnifications from x6 to x40. The Z-series slit lamp will only come with LED as a light source, the same as in cleared H-series device, but unlike the H-series slit lamp the bulb version will not be available for the Z-series. The modified device will offer converging and parallel viewing optics, the same options as available on the unmodified device. While the unmodified device has been cleared with converging viewing optics only and the parallel option has been added at a later stage, this design change has been thoroughly verified and validated internally during the course of this project, reports are available on request.
Z-type illumination tower with LED light source is brighter than H-series with 240k Lux, the change in light intensity has been appropriately assessed for optical radiation hazard and new exposure safety limits added to the IFU. The modified device complies with ISO 15004-2:2007 and other standards listed in the Standards Data Report.

1.4 Indications for Use

The following indications for use for the Keeler Slit Lamp Z-Series remain unchanged by introduction of the Z-type illumination tower, additional options of parallel optics and a choice of magnifications:

“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 “

1.5 Comparison with Cleared Device

The Keeler Slit Lamp has been modified to include a bottom illuminating system that comes with the same light source (LED) and the higher light output. The bulb version of the device is not available for the Keeler Slit Lamp Z-series. The modified device will have a choice of parallel and converging optics and 3x and 5x magnification block.

1.6 Summary of Design Control Activities

In accordance with FDA guidance on submission of a Special 510(k), risk management, verification/validation and other related activities were carried out to assure continuing safety and effectiveness of the device. In particular, the Keeler Slit Lamp Z-Series has been re-evaluated against ISO 15004-2/ISO 10939 for optical radiation hazard, IEC 60601-1 for electrical safety and IEC 60601-1-2 for electromagnetic compatibility.

For the purpose of safety testing the “worst case scenario” configuration was selected for Optical radiation hazard, electrical safety and EMC testing (Keeler Slit Lamp Z-series digital with parallel optics and 5x magnification), while verification/validation tasks were performed for all components used in all configurations.

In all tests, the Keeler Slit Lamp Z-series (including digital variant) was found to be in compliance with these FDA recognized standards.

1.7 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, including the digital version, with the bottom-illuminating projection system is safe and effective, and substantially equivalent to the unmodified versions of this device used as a predicate.