K100500

MAR - 9 2010

510(k) Summary

Submitter's information

The submitter of this pre-market notification is:

Mr. Eugene VanArsdale (Marketing Manager).
Keeler Instruments Inc
456, Parkway, Broomall, PA 19008
Company Phone No: (610) 353 4350
Company Fax No: (610) 353 7814

Date summary prepared: January 04, 2010

Device Identification

Device Trade Name:	Keeler PSL Classic Slit Lamp
Common Name:	Portable Slit Lamp
Class:	II
Classification Panel:	86
Product Code:	HJO
Regulation Number:	886.1850

Device description

The Keeler Portable Slit Lamp comprises a rechargeable hand held portable illuminated biomicroscope system and a desk mounted base charger unit that is powered from a low voltage (12V) power supply.

The hand held unit incorporates a built-in rechargeable battery powering the illumination system. The illumination system and fixation targets are activated using a single/double click trigger located on the front of the grip/handle. To increase or reduce the light intensity there is a rheostat located below the eyepieces on the rear of the grip /handle.

The 10 x and 16 x magnifications optical system is controlled using the lever located under the adjustable eyepieces.

Basic Principle of operation

The illumination system and fixation targets are activated using a single/double click trigger located on the front of the grip/handle. The construction of this slit lamp is such that light from a 15W filament lamp is relayed to the corneal plane via a lens and prism, the corneal plane being situated at 50mm from the output face of the prism. Filters or slits can be placed in the beam to vary the output in terms of colour and illuminated shape. Pupillary distance between the eye pieces, dioptric power of each eye piece and magnification can be adjusted as per requirement.
This instrument is used for non-invasive illumination, magnification and observation of the human eye.

Intended use

The slit lamp is an instrument consisting of a light source that can be focused to shine a thin sheet (slit) of light into the eye. It is used in conjunction with a biomicroscope. The lamp facilitates an examination of the anterior segment, or frontal structures and posterior segment, of the human eye, which includes the eyelid, sclera, conjunctiva, iris, natural crystalline lens, and cornea. The binocular slit-lamp examination provides stereoscopic magnified view of the eye structures in

detail, enabling anatomical diagnoses to be made for a variety of eye conditions. The Slit Lamp should be used only by suitably trained and authorised healthcare personnel.
The device and accessories are indicated as noninvasive aid in the examination and diagnosis of eye conditions and indications are the same as those claimed for predicate device

Substantial equivalence

Predicate Device: KOWA SL-15
510(k) No: K063640
Manufacturer: KOWA Company Ltd.

The Kowa Portable Slit Lamp SL-15 is chosen as a substantially equivalent device, with its similar intended use and its classification as a slit lamp. The predicate device is a hand-held slit lamp and is equipped with rechargeable battery. Similar to predicate device, Keeler Portable Slit Lamp is equipped with a rechargeable battery.
The Keeler Portable slit lamp has 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.

Technological characteristics

The technological characteristics are the same or similar to those found with the predicate device where eye is examined by projecting light onto it.

Declaration of device design

The Keeler Portable Slit Lamp has been designed using latest methods of evaluation and validation to ensure the risk of physical injury whilst performing the intended functions has been reduced as much is practicably possible.

Keeler Quality Approvals

Keeler is an ISO 9001:2000 and BS EN 13485:2003 compliant company and is obliged to ensure that our operating and design practices fully comply. As part of the design process, all necessary risk analysis, risk management, design verification and validation are conducted to ensure that the safety and effectiveness of product designs either meet or surpass the product specification and comply with the relevant standards.

Summary of Performance Testing

The performance of Keeler PSL Classic has been evaluated in Optical Radiation Safety Test, Electrical Safety Test, Electromagnetic Compatibility Test, comparative study with its predicative devices and field trial in clinical environment. The units under test met the acceptance criteria of the operating range and usability.

Based on the results of performance testing, the performance of Keeler PSL Classic is judged to be as safe, as effective and performs as well to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAR - 9 2010

Keeler Instruments, Inc.
c/o Mr. Jeff Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Dr.
Research Triangle, NC 27709

Re: K100500
Trade Name: Keeler PSL Classic Slit Lamp
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: February 19, 2010
Received: February 22, 2010

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Tesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological 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): K100500

Device Name: Keeler PSL Classic Slit Lamp

Indications For Use:

Keeler PSL Classic Slit Lamp is an AC-powered Slit lamp biomicroscope. It 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/5/2010

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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