K080776

Summary of Safety and Effectiveness for the GILRAS Slit Lamp

submitted by
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SEP - 9 2008

on behalf of

USOphthalmic
7255 NW 68th Street Unit # 9
Miami, FL 33166
Phone: (305) 969-4545

Contact Person:	Ezequiel D. Lukin
Device Trade Name:	GILRAS Slit Lamp
Common Name:	Slit Lamp
Classification Name:	Biomicroscope, Slit-lamp, AC-powered per 21 CFR § 886.1850

Identification of a Legally Marketed Predicate Device

The USOphthalmic GILRAS Slit Lamp is substantially equivalent to 66 Vision-Tech YZ Slit Lamp that is legally marketed and distributed by Suzhou 66 Vision-Tech Co., LTD pursuant to premarket notification K033190.

Device Description

The GILRAS Slit Lamp is an AC-power slit lamp biomicroscope intended for use in eye examination. There are 3 models GR-SL36, GR-SL54, and GR-SL72. These models differ only in the supplied accessories. All models have the same operating characteristics and intended use.

Intended Use

The GILRAS Slit Lamp is an AC-power slit lamp biomicroscope 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 affect the structural properties of the anterior eye segments.

Summary of Technological Characteristics

An 23-point comparison of the technological characteristics of the USOphthalmic GILRAS Slit Lamp and the predicate devices was performed. The devices were found to be substantially equivalent as shown in the table below.

Feature	GILRAS Slit Lamp	66 Vision-Tech YZ Slit Lamp
Manufacturer	**Manufacturer:** Shanghai MediWorks Precision Instruments, LTD **Relabeler:** USOphthalmic	Suzhou 66 Vision-Tech Co., LTD
Trade name	GILRAS Slit Lamp	66 Vision-Tech YZ Slit Lamp
510(k) Number	K080776	K033190
Intended use	The GILRAS Slit Lamp is an AC-power slit lamp biomicroscope 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 affect the structural properties of the anterior eye segments.	The 66 Vision-Tech YZ Slit lamp is an AC-power slit lamp biomicroscope 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.
Method of Operation	AC-powered	AC-powered
Exposure Parameters	50000 Lux Maximum Continuously adjustable from 0 to 50000 Lux	75000 Lux at position ¼ 150000 Lux at position ½ 300000 Lux at position 1
Data Collection and/or Display Systems	None	None
Flammability of Materials	Non-combustion supporting materials	Non-combustion supporting materials
Maximum temperature of Parts of the Device Held by the Operator or Accessible to the	30°C	30°C
Eyepiece Power	12.5X	12.5X
Total Magnification	GR-SL36 - 10X, 16X, 25X GR-SL54 - 6X, 10X, 16X, 25X, 40X GR-SL72 - 10X, 16X, 25X	6X, 10X, 16X, 25X, 40X
Stereo Angle	13°	13°
Diopter Adjustment	-6D to +6D	-5D to +3D
Pupillary Adjustment:	55mm to 78.5mm	55mm to 78.5mm
Slit Width	Continuous from 14mm to 0mm (at 14mm,slit becomes a circle)	Continuous from 9mm to 0mm (at 14mm,slit becomes a circle)

Feature	GILRAS Slit Lamp	66 Vision-Tech YZ Slit Lamp
Slit Length	Continuous from 14mm to 0mm (at 14mm,slit becomes a circle)	Continuous from 9mm to 0mm (at 14mm,slit becomes a circle)
Slit Angle	0 to 180 degree with horizontal scanning capability	0 to 180 degree with horizontal scanning capability
Aperture Diameters	14, 8, 5, 3, 0.5,and 0.2mm	9mm, 8mm, 5mm, 3mm, 2mm, 1mm, 0.2mm
Filters	Heat-absorbing, Neutral Density, Cobalt Blue, and Red-Free	Heat absorption, gray, red-free, and blue
Slit Inclination	5°, 10°, 15°, and 20°	5°, 10°, 15°, and 20°
Illumination Lamp	6V, 20W halogen lamp	12V, 30W halogen lamp
Hruby Lens	Not available	Optionally Available
Fixation Target	Green LED	Red LED
Brightness Controls	Continuously adjustable from 0 to 50000 Lux	3-mode: low, medium and high
Patient Contact Materials	Chin-rest paper Forehead-rest - Polytetrafluoroethylene	Chin-rest paper Forehead-rest - Polytetrafluoroethylene
Beam Splitter	GR-SL36 - No GR-SL54 - No GR-SL72 – Yes	Optional

Summary of Performance Data

The USOphthalmic GILRAS Slit Lamp complies with the requirements of listed FDA Recognized Consensus Standards.

- ISO 10939:2007, Ophthalmic instruments -- Slit-lamp microscopes
- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety

The USOphthalmic GILRAS Slit Lamp is substantially equivalent to the 66 Vision-Tech YZ Slit Lamp that is legally marketed and distributed by Suzhou 66 Vision-Tech Co., LTD. This has been demonstrated through a 8-point technological comparison of features.

Because the USOphthalmic GILRAS Slit Lamp meets the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2008

USOphthalmic, LLC
c/o Al Weisenborn
7255 NW 68th Street, Unit #9
Miami, FL 33166

Re: K080776
Trade/Device Name: GILRAS Slit Lamp, Models GR-SL36, GR-SL54 and GR-SL72
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slit-lamp Biomicroscope
Regulatory Class: II
Product Code: HJO
Dated: August 14, 2008
Received: August 15, 2008

Dear Mr. Weisenborn:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

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

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510(k) Number (if known): K080776

Device Name: GILRAS Slit Lamp

Indications for Use:

The GILRAS Slit Lamp is an AC-power slit lamp biomicroscope 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 affect the structural properties of the anterior eye segments.

Prescription Use X AND/OR Over-The-Counter Use
(Per 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)

Daryl L. Kaufman

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

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