K063416

Summary of Safety and Effectiveness for the Luxvision Slit Lamp

DEC - 7 2006

submitted by
USOphthalmic
7255 NW 68th Street Unit # 9
Miami, FL 33186
Phone: (305) 969-4545

Contact Person: Ezequiel D. Lukin
Device Trade Name: Luxvision 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 Luxvision 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 Luxvision Slit Lamp is an AC-power slit lamp biomicroscope intended for use in eye examination There are 3 models LS880, LS1100, and LS1400. These models differ only in the supplied accessories. All models have the same operating characteristics and intended use.

Intended Use

The Luxvision 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 8-point comparison of technological characteristics of the USOphthalmic Luxvision Slit Lamp and the predicate devices was performed. The devices were found to be substantially equivalent.

Summary of Performance Data

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

- ISO 10939:1998, Ophthalmic instruments -- Slit-lamp microscopes
- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety

The USOphthalmic Luxvision 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 Luxvision 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

DEC - 7 2006

U. S. Ophthalmic LLC
c/o Mr. Al Weisenborn
7255 NW 68th St. Unit #9
Miami, FL 33166

Re: K063416
Trade/Device Name: Luxvision Slit Lamp (Models LSL880, LSL 1100, and LSL 1400)
Regulation Number: 21 CFR 886.1850
Regulation Name: Slit Lamp
Regulatory Class: II
Product Code: HJO
Dated: November 3, 2006
Received: November 13, 2006

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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.
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): K063416

Device Name: Luxvision Slit Lamp

Indications for Use:

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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

510(k) Number K063416

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