K110489

MAY 2 3 2011

510(k) SUMMARY

Topcon Medical Systems, Inc.
Slit Lamp SL-2G

510(k) Owner's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: February 18, 2011

Trade Name of Device

Topcon Slit Lamp SL-2G

Common or Usual Name

AC- Powered Slit-Lamp Biomicroscope

Classification Name

AC-powered slitlamp biomicroscope; 21 C.F.R. 886.1850
Class II
Product Code: HJO

Predicate Devices

Haag-Streit AG BM 900/BQ 900/ BP 900 (K100202)
Haag-Streit AG BC 900 (K982057)

Device Description

The Slit Lamp SL-2G is an AC-powered device that is a microscope intended for use in eye examination that projects into a patient's eye through a control diaphragm a thin, intense beam of light. The Slit Lamp SL-2G is composed of the following components: microscope unit, illumination unit, base unit, chinrest, table and power unit. The slitlamp biomicroscope is used for the observation of the eye. It has an illumination unit to illuminate the eye, and a binocular stereoscopic microscope to zoom and observe patient's eyes, and also can observe the three-dimensional image.

Intended Use / Indications for Use

The Slit Lamp SL-2G is an AC-powered slitlamp 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 segment.

Performance Data

The Slit Lamp SL-2G conforms to following standards: IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991; Amendment 2, 1995; IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, Edition 3:2007; ISO 15004-1:2006 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments;, ISO 15004-2:2007 Ophthalmic Instruments - Fundamental requirements and test methods Part 2: Light hazard protection and ISO 10939:2007 Ophthalmic Instruments-Slit Lamp Microscopes.

Substantial Equivalence

The Topcon Slit Lamp SL-2G is substantially equivalent to the predicate devices, the HAAG-STREIT Slit Lamps BM 900/BQ 900/BP 900 (K100202) and BC 900 (K982057).

The Slit Lamp SL-2G and the predicated devices have the same intended use and indications for use as the predicate devices. The intended use for the Slit Lamp SL-

2G and the identified predicate devices is to examine the anterior eye segment for diagnostic purposes. The Topcon Slit Lamp SL-2G has similar technological characteristics to the predicate devices. The Slit Lamp SL-2G and the predicate devices are all AC-powered slit lamp biomicroscopes that project a beam of light into the patient's eye through a control diaphragm. Exposure parameters including slit image width, slit image length, illumination field diameter and slit direction are all within the specifications of the previously cleared predicate devices. The light source for the SL-2G is an LED which is one of the available light sources for the BM 900/BQ 900/BP 900 series of slit lamps. In the Topcon Slit Lamp SL-2G the maximum brightness of the LED is 160,000 Lux while in the Haag Streit slit lamps the maximum brightness is up to 450,000 Lux. Both the Topcon Slit Lamp SL-2G and the BP 900 have the same magnification steps and eyepiece lens magnification. The Slit Lamp SL-2G conforms to the same recognized performance standards as the predicate devices which further demonstrates substantial equivalence. Therefore, the Slit Lamp SL-2G is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Topcon Medical Systems, Inc.
c/o Ms. Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

MAY 23 2011

Re: K110489
Trade Name: Topcon Slit Lamp SL-2G
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: February 18, 2011
Received: February 22, 2011

Dear Ms. O'Connell:

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,

Deborah Falls

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 Statement

510(k) Number (if known): K110489

Device Name: Topcon Slit Lamp SL-2G

Indications for Use:

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Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807
Subpart C)

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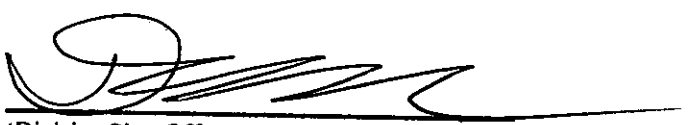
Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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