DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 9, 2016

Topcon Corporation
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K161972
Trade/Device Name: Slit Lamp SL-D301
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: November 7, 2016
Received: November 8, 2016

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 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,

Denise L. Hampton -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)*

Device Name
Slit Lamp SL-D301

Indications for Use *(Describe)*
The Slit Lamp SL-D301 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.

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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510(k) SUMMARY

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Slit Lamp SL-D301

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Date Prepared: December 9, 2016

Trade Name of Device
Slit Lamp SL-D301

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
TOPCON CORPORATION Slit Lamp SL-D701 (K133667)

Device Description
This instrument is a slit lamp to observe, examine and photograph the eyeball and appendage of the eye. The slit lamp has the illumination unit for illumination and the binocular stereo microscope, and allows for stereoscopic observation. This instrument allows users to photograph and save the observed

images by combining with an accessory, the digital camera unit DC-4. This instrument consists of the main body and accessories.

Intended Use / Indications for Use

The Slit Lamp SL-D301 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.

Substantial Equivalence

The Slit Lamp SL-D301 is substantially equivalent to Topcon's Slit Lamp SL-D701 cleared in K133667**.** The Slit Lamp SL-D301 has the same intended use and indications for use, and similar principles of operation and technological characteristics as the previously cleared predicate device**.**

The Topcon Slit Lamp SL-D301 has similar technological characteristics to the predicate device. The Slit Lamp SL-D301 and the predicate device are both 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 device. The slit image width is 0-9 mm in the Slit Lamp SL-D301 and 0-14 mm in the SL-D701. The slit image length is 1-8 mm in the Slit Lamp SL-D301 and 1-14 mm in the SL-D701. These ranges are in compliance with ISO 10939:2007 and differences are not significant.

The light source for the Slit Lamp SL-D301 is a Halogen Bulb. In the Topcon Slit Lamp SL-D301 the maximum brightness of the Halogen Bulb is 230,000 Lux while in the SL-D701 the maximum brightness is up to 450,000 Lux. Both the Topcon Slit Lamp SL-D301 and SL-D701 have the same magnification steps and eyepiece lens magnification.

Both the Topcon Slit Lamp SL-D301 and the SL-D701 cleared in K133667 comply with the following consensus standards: IEC 60601-1, IEC60601-1-2, ISO 15004-2:2007 and ISO 10939:2007.

The Slit Lamp SL-D301 has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicate. Thus, the Slit Lamp SL-D301 is substantially equivalent to its predicate.

Performance Data

The following bench testing was conducted in order to demonstrate compliance with recognized consensus standards:

- AAMI ANSI/ES60601-1:2005/(R)2012 and C1:2009(R)2012 and A2:2010(R)2012 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance;
- IEC 60601-1-2: 2007 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance: Collateral Standard: Electromagnetic Capability – Requirements and Tests;
- 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;
- ISO 10939:2007 Ophthalmic Instruments – Slit-lamp microscopes;

The performance testing demonstrated that the Slit Lamp SL-D301 is as safe and effective as the predicate device, and performs as well or better than the predicate. The test results showed that the Slit Lamp SL-D301 met the same electrical safety, optical safety and slit lamp standards as the predicate device.