DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 19, 2017

Nidek Co., Ltd.
Toshio Murata
Senior RA/QA Manager
Nidek Inc.
47651 Westinghouse Drive
Fremont, CA94539

Re: K163564
Trade/Device Name: Slit Lamp SL-2000
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: April 7, 2017
Received: April 10, 2017

Dear Toshio Murata:

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)*
K163564

Device Name
SLIT LAMP SL-2000

Indications for Use *(Describe)*
The SLIT LAMP SL-2000 is intended for use in eye examination of the anterior eye segment, from the corneal epithelium to the posterior capsule. This device 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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NIDEK CO., LTD.
34-14, Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments

TEL +81-533-67-6611
FAX +81-533-67-6610
URL http://www.nidek.co.jp
http://www.nidek.com

K163564

510(K) SUMMARY

GENERAL INFORMATION

Applicant:

NIDEK CO., LTD.
34-14 Maehama, Hiroishi-cho,
Gamagori, Aichi, 443-0038
Japan
Phone: +81-533-67-8901
Fax: +81-533-67-6628

Contact Person:

Toshio Murata
Senior RA/QA Manager
NIDEK INC.
47651 Westinghouse Drive
Fremont, CA 94539
U.S.A.
Phone: 510-353-7789
FAX: 510-226-5750

Date Prepared: May 16, 2017

DEVICE INFORMATION

Trade Name:

SLIT LAMP SL-2000

Generic/Common Name:

AC-powered Slitlamp Biomicroscope

Classification:

21 CFR §886.1850, Class II

Classification panel:

Ophthalmic

Product Code:

HJO

PREDICATE DEVICE(S)

- SL 130 Slit Lamp, Carl Zeiss Meditec AG. (K133476)
- Slit Lamp H-Series Digital, Keeler Limited (K140451)

INDICATIONS FOR USE

The SLIT LAMP SL-2000 is intended for use in eye examination of the anterior eye segment, from the corneal epithelium to the posterior capsule. This device is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

PRODUCT DESCRIPTION

The SLIT LAMP SL-2000 is used to magnify the eyeball, eyelid, and eyelash of patients for observation, using slit illumination light.

The SL-2000 comprises the main unit that incorporates the microscope unit, illumination unit, base plate unit, and power supply box.

Comparison of technological characteristics with predicate devices

The SL-2000 and the predicate devices are all slit lamps that are intended for use in eye examination of the anterior eye segment, from the corneal epithelium to the posterior capsule. All these devices are Galilean type slit lamps with converging binoculars.

The SL-2000 is provided with eyepieces 12.5× as the predicate devices are and optional eyepieces 16× with which the predicate devices are not provided. Because the range of the total magnification of the SL-2000 with eyepieces 16× is equivalent to that of the predicate devices, use of optional eyepieces 16× does not raise new safety or effectiveness questions.

The range of the field of view diameter of the SL-2000 is almost equivalent to that of the Zeiss SL 130 Slit Lamp. In addition, the real field of view diameters were verified and found to comply with the specifications.

The SL-2000 compensates ametropia of ±8 D as the predicate devices do.

The SL-2000 allows interpupillary adjustment in the range of 50 mm to 78 mm. Although there is a difference in the range of adjustment between the SL-2000 and predicate devices, this does not affect the safety and effectiveness because the SL-2000 and the predicate devices meet the range for interpupillary adjustment of 55 mm to 72 mm required in ISO10939:2007.

With regard to illumination, the width of slit image, slit rotation, angle of incidence, and brightness control method are the same between the SL-2000 and Zeiss SL 130 Slit Lamp. The range of length of slit image of the SL-2000 falls within that of the predicate devices. The SL-2000 as well as Keeler Slit Lamp H-Series Digital uses an LED as a light source and all the devices comply with ISO 15004-2. The SL-2000 is provided with the blue, red free, neutral density filters, and barrier filter for fluorescent observation (yellow filter) as the predicate devices are. Although the IR cut filter of the SL-2000 does not absorb heat, the filter does not need to have such a characteristic because the LED of the SL-2000 does not emit infrared rays (heat rays).

As mentioned, the minor differences in specifications between the SL-2000 and the predicate devices do not raise new questions of safety and effectiveness and do not adversely affect the safety and effectiveness of the device.

SUBSTANTIAL EQUIVALENCE

The SLIT LAMP SL-2000 is substantially equivalent to the predicate devices, Carl Zeiss Meditec AG., SL 130 Slit Lamp, Keeler Limited Slit Lamp H-Series Digital.

The SL-2000 is similar in technological characteristics, performance, and principles of operation and has similar indications for use as the predicate devices. Any differences in technological characteristics between the proposed device and the predicate devices do not

raise any new issues of safety or effectiveness. Thus, the SL-2000 is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the SLIT LAMP SL-2000 to support a determination of substantial equivalence to the predicate devices. The tests performed include:

- Ophthalmic Testing per ISO 15004-1 and ISO 15004-2
- Testing per ISO 10939
- Software Verification and Validation
- Usability Testing per IEC 60601-1-6 and IEC 62366
- Electrical Safety Testing per AAMI/ANSI ES60601-1 and Electromagnetic Compatibility Testing per IEC 60601-1-2.

The collective performance testing demonstrates that the SL-2000 does not raise any new questions of safety or effectiveness when compared to the predicate devices. The results of the performance testing demonstrate that the SL-2000 performs as intended and does not raise any new questions of safety or effectiveness.

CONCLUSION

In summary, NIDEK CO., LTD. is of the opinion that the SLIT LAMP SL-2000 does not introduce any new potential safety risks, is as effective and performs as well as the predicate devices, and concludes that the SL-2000 is substantially equivalent to the predicate devices.

SUMMARY

The SLIT LAMP SL-2000 is substantially equivalent to the predicate devices.