



NIDEK CO., LTD.

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Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments

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7. 510(K) SUMMARY

This summary of the 510(k) premarket notification for the Nidek Green Laser Photocoagulator Model GYC-1000 connected with the Endophotocoagulation Delivery Unit (for sterilized endophoto probe) is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

510(k) Notification K 131894

GENERAL INFORMATION

Applicant:

NIDEK CO., LTD.
34-14 Maehama, Hiroishi
Gamagori, Aichi, 443-0038 Japan

OCT 31 2013

Contact Person: Yoneji Mizuno
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Date Prepared: June 20, 2013

Classification:

21 CFR § 878.4810, Class II

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Proprietary and Confidential Information

Special 510(k)
GYC-1000 connected with Endophotocoagulation Delivery Unit (for sterilized endophoto probe)
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Classification name:

Laser surgical instrument for use in general and plastic surgery and in dermatology

Product Code:

GEX

Trade Name:

GREEN LASER PHOTOCOAGULATOR MODEL GYC-1000 connected with the Endophotocoagulation Delivery Unit (for sterilized endophoto probe)

Generic/Common Name:

Powered laser surgical instrument

Predicate Device

Nidek Green Laser Photocoagulator Model GYC-1000 (K032085)

Indications for use

The Nidek Green Laser Photocoagulator Model GYC-1000 is indicated for use in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

Product Description

Nidek Green Laser Photocoagulator Model GYC-1000 connected with the Endophotocoagulation Delivery Unit (for sterilized endophoto probe) is an ophthalmological photocoagulation system using a solid state laser (green laser beam) with a wavelength of 532nm. Like conventional laser photocoagulation systems, this system is used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty when a delivery unit such as the Endophotocoagulation Delivery Unit is connected.

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GYC-1000 connected with Endophotocoagulation Delivery Unit (for sterilized endophoto probe)
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Special 510(k)

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Substantial Equivalence

The GYC-1000 connected with the proposed Endophotocoagulation Delivery Unit (for sterilized endophoto probe) is substantially equivalent to the predicate device with regard to design, function, technological characteristics, intended use and performance characteristics.

The differences between the proposed and old Endophotocoagulation Delivery Units and justifications as to why these differences do not raise safety or efficacy concerns are as follows:

- 23G and 25G sterilized endopho probes were added to the proposed device and available as options. They have been FDA cleared (k 021696).
- The fiber core diameter at the end of the probe tip was reduced to 300 μm for 20G or 23G probe and 200 μm for 25G probe from 400 μm . The smaller fiber core diameter will result in increase in the power per unit size. As the probe is moved closer to the retina, the beam diameter becomes smaller. On the other hand, as the probe is moved away from the retina, the beam diameter becomes larger. In practice, the surgeon adjusts the beam diameter by moving the probe before emission of the laser. Therefore, the change in fiber core diameter raises no new issues of safety or efficacy.
- Cone angle, the degree the laser beam that disperses from the aperture of the probe, was changed from 11 $^{\circ}$ or less to 12.5 $^{\circ}$ or less. The cone angle is dependent on the used fiber, rather than on the gauge of the endophoto probe. As the probe is moved away from the retina, the beam diameter becomes larger. On the other hand, as the probe is moved closer to the retina, the beam diameter becomes smaller. In practice, the surgeon adjusts the beam diameter by moving the probe before emission of the laser. Therefore, the change in cone angle because of the change of the probes raises no new issues of safety or efficacy.



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- Fixed protective filter was added to the proposed device and available as an option. The major specifications such as guard wavelength, and optical density for the added fixed protective filter are the same as those for the electrically-powered and manual protective filters except for operation principle, dimensions, mass and its cable length.

The design modifications outlined in this Special 510(k) premarket notification do not (1) affect the intended use or the indication for use or (2) alter the fundamental scientific technology of the device. The proposed Endophotocoagulation Delivery Unit shares the same indications for use, the same technological characteristics and the same principle of operation as the old Endophotocoagulation Delivery Unit of the predicate device. Therefore, based on the similarities between the two devices, the proposed Endophotocoagulation Delivery Unit is substantially equivalent to the old Endophotocoagulation Delivery Unit covered by the cleared GYC-1000 (K032085) as the predicate device.

Testing in Support of Substantial Equivalence Determination

We have verified and validated that the GYC-1000 connected with the proposed Endophotocoagulation Delivery Unit (for sterilized endophoto probe) meets its functional specifications and performance requirements, and complies with applicable international standards (IEC 60601-1, 60601-1-2, 60601-2-22, 60825-1, ISO10993-1).

As mentioned, all necessary bench testing was conducted on the modifications, the addition of the proposed Endophotocoagulation Delivery Unit (for sterilized endophoto probe) to support a determination of substantial equivalence to the predicate device.

Summary

The Nidek Green Laser Photocoagulator Model GYC-1000 connected with the proposed Endophotocoagulation Delivery Unit (for sterilized endophoto probe) is substantially equivalent to the predicate device.



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

NIDEK Corporation, LTD.
Yoneji Mizuno
Senior Manager, Regulatory Affairs
34-14 Maehama Hiroishi-cho
Gamagori, Aichi
China

October 31, 2013

Re: K131894

Trade/Device Name: GREEN LASER PHOTOCOAGULATOR MODEL GYC-1000
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general
and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 6, 2013
Received: October 13, 2013

Dear Mizuno:

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

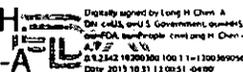
CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control 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 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>. 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 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,

Long H. Chen
Chen - A



for MXM

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K131894

Device Name: Nidek Green Laser Photocoagulator Model GYC-1000 connected with the Endophotocoagulation Delivery Unit (for sterilized endophoto probe)

Indications For Use:

The Nidek Green Laser Photocoagulator Model GYC-1000 is indicated for use in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Neil R Ogden 
2013.10.31 10:40:28 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K131894