DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 2, 2016

Nidek Incorporated
℅ Mr. Toshio Murata
Regulatory Affairs Manager
47651 Westinghouse Drive
Fremont, CA 94539-7474

Re: K152603
Trade/Device Name: Green Laser Photocoagulator GYC - 500
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: March 28, 2016
Received: March 30, 2016

Dear Mr. 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 yours,

Kesia Alexander

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)*
K152603

Device Name
Green Laser Photocoagulator GYC-500

Indications for Use *(Describe)*
The Green Laser Photocoagulator GYC-500 is intended to be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

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

510(k) Notification K152603

GENERAL INFORMATION

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Date Prepared: September 8, 2015

DEVICE INFORMATION

Trade Name:
Green Laser Photocoagulator GYC-500

Generic/Common Name:
Ophthalmic laser

Classification:

21 CFR §886.4390, Class II

Product Code:

HQF

PREDICATE DEVICE(S)

- GREEN LASER PHOTOCOAGULATOR MODEL GYC-1000 (K032085)
- Multicolor Laser Photocoagulator System MC-500 (K110228)
- MULTICOLOR SCAN LASER PHOTOCOAGULATOR MC-500 Vixi (K111493)

INDICATIONS FOR USE

The Green Laser Photocoagulator GYC-500 is intended to be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

PRODUCT DESCRIPTION

The Green Laser Photocoagulator GYC-500 ("GYC-500") is a laser photocoagulator for ophthalmology using the 532 nm diode-pumped solid-state laser (green laser beam) as the treatment beam and 635 nm diode laser (red laser beam) as the aiming beam. Like other conventional laser photocoagulation system, the GYC-500 can be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty. The GYC-500 is a modified version of the GYC-1000 which was the subject of premarket notification number K 032085.

The GYC-500 is mainly comprised of the main body that incorporates a laser source, the control box that controls laser emission, and a delivery unit that guides the laser beam emitted from the main body to the patient's eye.

To use the GYC-500, the operator sets laser irradiation conditions such as laser output and laser application time according to the condition of treatment site through the control box of the GYC-500 or operation part of the connected delivery unit. When using a (attachable) slit lamp delivery unit, the operator observes the treatment site with the slit lamp, and aligns the treatment beam and aiming beam to the site. Then the operator presses the foot switch to

emit the treatment beam and aiming beam to the treatment site from the exit end of the GYC-500 system in a READY status while observing the operative field with the slit lamp. As the treatment beam is optically coaxial to the aiming beam, alignment is achieved when the user aligns the aiming beam to the treatment site. When the foot switch is pressed under the condition, the treatment beam of the set spot size is irradiated at which the aiming beam is projected. The operator can also select the laser irradiation pattern from a single laser spot and multiple laser spots in a predetermined pattern in a scanning manner.

Various types of the delivery units are available for the GYC-500. As the delivery units using a slit lamp, broadly speaking, two types of delivery units are available. One is called “Slit lamp delivery unit” integrating a slit lamp and a laser delivery unit. The other is called “Attachable delivery unit” that is the laser delivery unit integrating a protective filer and so on for connection to the slit lamp owned by the user. Either the slit lamp delivery units or attachable delivery units are divided into three types: 1) the unit only with the fixed protective filter that remains inserted into the optical path and without the micromanipulator (used for fine adjustment of the laser beam position), 2) the unit with the fixed protective filter or electrically-powered one (either filter is factory configured) and with the micromanipulator, and 3) the unit only with the electrically-powered protective filter, with the micromanipulator, and with the spot size control which is different from the aforementioned two types in mechanical structure.

Furthermore, the slit lamp delivery units are classified into “Slit lamp delivery unit” that delivers a single laser spot only, and “Scan slit lamp delivery unit” that delivers multiple laser spots in a predetermined pattern while scanning the laser spots as well as the single laser spot. In a similar manner, the attachable delivery units are further classified into “Attachable slit lamp delivery unit” that delivers a single laser spot only, and “Scan attachable slit lamp delivery unit” that delivers multiple laser spots in a predetermined pattern while scanning the laser spots as well as the single laser spot. The GYC-500 connected with a scan (attachable) delivery unit is called “Green Scan Laser Photocoagulator GYC-500 Vixi”.

Various slit lamp delivery units are available that allow for the adaptation of the GYC-500 to a slit lamp. A fiber optic cable is connected from the GYC-500 main body to the slit lamp,

thereby allowing the laser beam to be sent to the delivery unit. With the delivery unit, the patient can be treated in a seated position. The following slit lamp types are available: Slit lamp delivery unit (NIDEK SL-1800 type), Scan slit lamp delivery unit (NIDEK SL-1800 type), Attachable delivery unit (NIDEK SL-1800/SL-1600 type, ZEISS SL 130 type, ZEISS 30 SL/M type, HAAG 900BM/900BQ type), and Scan attachable delivery unit (NIDEK SL-1800/SL-1600 type, ZEISS SL 130 type, ZEISS 30 SL/M type, HAAG 900 BQ type).

Other than the (scan and/or attachable) slit lamp delivery units, a binocular indirect ophthalmoscope (B.I.O.) delivery unit and a combination delivery unit are available.

The B.I.O. delivery unit allows the operator to perform photocoagulation while observing the fundus with a binocular indirect ophthalmoscope. With the delivery unit, the patient can be treated in a supine position. The B.I.O. delivery unit (Heine Omega 500 type and Keeler All Pupil II type) connects to the GYC-500 main body via a fiber optic cable. The B.I.O. delivery unit consists of a binocular indirect ophthalmoscope (with headband), a 20 D condensing lens illumination lamp, and stand. The headband fits over the operator's head and has height and circumference adjustment knobs. A working distance control sets the working distance, which can be varied within a range of 300 to 700 mm. The treatment and aiming laser spot size can also be selected by changing working distance (with the 20D condensing lens).

The combination delivery unit is mounted on the NIDEK Ophthalmic YAG Laser System YC-1800's slit lamp and is connected to the GYC-500 main body using a connecting cable and a fiber-optic cable. The delivery unit allows the operator to perform photocoagulation using the green laser beam (532 nm) or photodisruption using an Nd: YAG laser beam while performing observation of the eye with the slit lamp of the YC-1800. The optical path for the green laser beam is completely independent from that for the Nd: YAG laser pulse beam. The operator selects the laser beam to be emitted by switching the optical path using the laser beam selector of the delivery unit. This delivery unit is intended to save the area occupied by the slit lamp for the GYC-500 and that for the YC-1800 by using the slit lamp of the YC-1800 consistently for both photocoagulation and photodisruption.

The delivery units allow transpupillary photocoagulation using a slit lamp or binocular

indirect ophthalmoscope. The operator chooses the optimal delivery unit for the purpose of photocoagulation of the patient's eye.

SUBSTANTIAL EQUIVALENCE

The GYC-500 is substantially equivalent to the predicate devices, Green Laser Photocoagulator Model GYC-1000, Multicolor Laser Photocoagulator System MC-500, and Multicolor Scan Laser Photocoagulator MC-500 Vixi. They are all laser photocoagulators that emit a laser-diode-pumped solid-state laser of 532 nm.

The GYC-500 is similar in technological characteristics, performance, 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 GYC-500 is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the Green Laser Photocoagulator GYC-500 to support a determination of substantial equivalence to the predicate devices. The tests performed include:

- Ophthalmic Testing per ISO 15004-1, and ISO15004-2
- Slit Lamp Testing per ISO 10939
- Laser Product Safety Testing per IEC 60601-2-22 and IEC 60825-1
- Software Verification and Validation
- Usability Testing per IEC60601-1-6 and IEC 62366
- Electrical Safety Testing per IEC60601-1 and Electromagnetic Compatibility Testing per IEC60601-1-2.

The collective performance testing demonstrates that the GYC-500 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 GYC-500 performs as intended and does not raise any new questions of safety or effectiveness.

510(K) SUMMARY (CONT.)

CONCLUSION

In summary, NIDEK CO., LTD. is of the opinion that the Green Laser Photocoagulator GYC-500 does not introduce any new potential safety risks, is as effective and performs as well as the predicate devices, and concludes that the GYC-500 is substantially equivalent to the predicate devices.

SUMMARY

The Green Laser Photocoagulator GYC-500 is substantially equivalent to the predicate devices.