March 31, 2021

Nidek Co., Ltd.
% Todd Milholland
RA/QA Director
Nidek Incorporated
2040 Corporate Court
San Jose, California 95131

Re: K203130
Trade/Device Name: Ophthalmic Yag Laser System YC-200
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF, HJO

Dear Todd Milholland:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 7, 2020. Specifically, FDA is updating this SE Letter as an administrative correction due to revisions in the 510(k) summary.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Elvin Ng, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, (240) 402-4662, elvin.ng@fda.hhs.gov.

Sincerely,

Alexander Beylin -S 2021.04.01 10:34:04 -04'00'

for Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

December 7, 2020

Nidek Co., Ltd.
% Todd Milholland
RA/QA Director
2040 Corporate Court
San Jose, CA 95131

Re: K203130
Trade/Device Name: Ophthalmic YAG Laser System YC-200
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF, HJO
Dated: October 15, 2020
Received: October 19, 2020

Dear Todd Milholland:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer N. Brown -S

for LT Charles Chiang
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203130

Device Name
OPHTHALMIC YAG LASER SYSTEM YC-200

Indications for Use *(Describe)*
The OPHTHALMIC YAG LASER SYSTEM YC-200 consists of a slit lamp and the YAG Laser and is indicated for the performance of posterior capsulotomy, posterior membranectomy, pupillary membranectomy, iridotomy (hole in the iris) and selective laser 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Number – K203130

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:

Todd Milholland

RA/QA Director

NIDEK INCORPORATED

2040 Corporate Court

San Jose, CA 95131

U.S.A.

Phone: 408-705-6356

Date Prepared: October 15, 2020

DEVICE INFORMATION

Trade Name:

OPHTHALMIC YAG LASER SYSTEM YC-200

Generic/Common Name:

Ophthalmic laser, AC-powered slit-lamp biomicroscope.

Classification:

21 CFR §886.4390, Class II

Product Code:

HQF, HJO

PREDICATE AND REFERENCE DEVICES

- NIDEK OPHTHALMIC YAG LASER SYSTEM YC-200 (as the primary predicate device)(K192045)
- Ellex Medical Pty. Ltd. LUMENIS SELECTA DUET (as a predicate device)(K021550)
- NIDEK Green Laser Photocoagulator GYC-500 (as a reference device)(K152603)

INDICATIONS FOR USE

The OPHTHALMIC YAG LASER SYSTEM YC-200 consists of a slit lamp and the YAG Laser and is indicated for the performance of posterior capsulotomy, posterior membranectomy, pupillary membranectomy, iridotomy (hole in the iris) and selective laser trabeculoplasty.

PRODUCT DESCRIPTION

The OPHTHALMIC YAG LASER SYSTEM YC-200 is an ophthalmic pulsed laser system using a 1,064 nm Q-switched pulsed Nd: YAG laser as the treatment beam source. The system consists of two types, differing only in the available types of laser emission. The two types are collectively referred to as "YC-200" throughout this 510(k). The operation mode(s) available differs depending on the type.

Type name	Model name	Emitted laser (wavelength)	Operation mode available
YC-200	YC-200	Nd: YAG laser (1,064 nm)	YAG mode
YC-200 S Plus	YC-200	Nd: YAG laser (1,064 nm) SLT laser (532 nm)	YAG mode SLT mode

As shown in the above table, the YC-200 S Plus provides the operator with two treatment modes, YAG mode and SLT mode, whereas the YC-200 type provides the operator with a single treatment mode, YAG mode.

In YAG mode, treatment using the YAG treatment beam whose wavelength is 1,064 nm is available. This mode is used mainly for posterior capsulotomy and iridotomy. The 360-degree rotating two-aiming-beam system that separates the YAG aiming beam into two beams is

used. The focus position is determined according to the alignment of the beams. In YAG mode, single irradiation mode and burst mode are available. In single mode, one shot of the treatment beam is emitted each time the trigger switch is pressed, whereas in burst mode, two or three shots of the treatment beam are emitted each time the trigger switch is pressed. In YAG mode, the focus shift function to shift the focal points of the YAG treatment beam on the basis of the YAG aiming beam is available. This function allows the operator to shift the focal point of the YAG beam to the posterior chamber side compared to the aiming beam in order to prevent pitting of the intraocular lens.

In SLT mode, treatment using the YAG treatment beam whose wavelength is 532 nm is available. This mode is used for selective laser trabeculoplasty. In this mode, a parfocal optical system is used. In the parfocal optical system, the image of an object surface is formed on the target surface. The SLT aiming beam is emitted from the fiber tip (the object surface) so that it appears as a sharply-edged spot on the target surface. The focus position is determined according to the projection status of the beams. In SLT mode, SLT-NAVI assists the operator in surgery by specifying the laser emission positions and sequence before the treatment is available. The progress status of laser treatment is intuitively displayed in real time in the SLT-NAVI area of the main screen based on the premise that the treatment is proceeding as scheduled.

The system is mainly comprised of the YC-200 main body that incorporates a laser source, and a slit lamp that is similar to the previously cleared SL-2000 (K163564), a head rest, a control box that controls laser emission, and a connector box.

To use the YC-200, the operator should first adjust the focus of the eyepieces to the operator's refractive error and adjusts the eyepieces to the operator's pupillary distance. The operator instructs the patient to place his or her chin on the chinrest, to rest his or her forehead on the forehead rest, and to hold the grips. The operator aligns the level of the patient's eye with the eye level marker, fasten the patient's head with the head belt, and instructs the patient to look at the fixation lamp to stabilize his or her visual axis. The operator looks through the microscope to observe the treatment site. The operator sets laser emission conditions such as laser power output through the control box of the YC-200, turns on the aiming beam, and set the YC-200 to the READY mode. Alignment is achieved when the operator adjusts the joystick

and contact lens to align the aiming beam focus with the target position. Finally, the operator presses the hand switch or depresses the optional foot switch to emit the treatment beam in the READY mode while observing the operative field with the slit lamp.

One of the reasons for this 510(k) submission is to add the combination delivery unit to connect the subject device to the GYC-500 previously cleared in 510(k) No. K152603.

The combination delivery unit allows the operator to perform photocoagulation using the green laser beam (532 nm) or photodisruption using the Nd: YAG laser pulse beam (1064 nm, hereafter referred to as "YAG laser beam") or SLT laser (532 nm, for YC-200 S plus only) while observing the patient's eye with the slit lamp of the YC-200. The delivery unit is connectable to the previously cleared Green Laser Photocoagulator GYC-500, and the subject YC-200. The photocoagulation unit of the combination delivery unit is mounted on the subject YC-200's slit lamp and is connected to the GYC-500 main body using a connecting cable and a fiber-optic cable.

The operator selects the laser beam to be emitted by switching the optical path using the laser beam selector of the combination delivery unit. The optical path of the combination delivery unit for the green laser beam is completely independent from that of the subject YC-200 for the Nd: YAG laser beam. When "YC" is selected by the laser beam selector to select the laser beam to be emitted, the laser refractive mirror is stored in the photocoagulation unit of the delivery unit. When "COAG" is selected by the laser beam selector, the laser refractive mirror comes out from the photocoagulation unit.

When the combination delivery unit is attached to the YC-200 and connected to the previously cleared GYC-500 (510(k) No. K152603), the YC-200 works strictly as a diagnostic slit lamp – all photodisruptor and SLT laser functions are disabled.

The combination delivery unit is comprised of the photocoagulation unit, and protective filter. The photocoagulation unit adjusts the spot size of the treatment beam and aiming beam emitted from the GYC-500, while the protective filter protects the operator's eye from the reflected green laser beam that can be emitted only when the protective filter is inserted in the optical path.

The green laser beam from the GYC-500 requires a delivery unit to be delivered to the patient's eye. The green laser beam is delivered to the patient's eye via the combination delivery unit when it is mounted on the YC-200. The combination delivery unit is intended to save the area occupied by the slit lamp of delivery unit for the GYC-500 by using the slit lamp of the YC-200 consistently during both photocoagulation and photodisruption.

Another reason for this 510(k) submission is to add "posterior membranectomy" is to expand treatment options. With the addition of "posterior membranectomy" to the indications for use, the split mirror illumination tower for posterior membranectomy is added as an optional accessory. The split mirror illumination tower was designed to irradiate the target with slit illumination so that the slit illumination is made incident from the center while allowing the YAG treatment beam to pass between the upper and lower mirrors. The previously cleared illumination tower equipped with a tilting function for SLT mode, and illumination tower with the base fixed for YAG mode do not allow the treatment beam to be delivered to the posterior segment of the eye while the operator observes the posterior segment because these illumination towers themselves interrupt the YAG treatment beam. Thus, the previously cleared ones are inappropriate for posterior membranectomy.

SUBSTANTIAL EQUIVALENCE

The YC-200 is equivalent to the predicate devices, NIDEK OPHTHALMIC YAG LASER SYSTEM YC-200, and Ellex Medical Pty. Ltd. LUMENIS SELECTA DUET. The YC-200, and the predicate devices are Nd:YAG photodisruptor laser and Selective Laser Trabeculoplasty (hereafter referred to as "SLT") laser intended for use in ophthalmic surgical procedures, including posterior capsulotomy, iridotomy, and selective laser trabeculoplasty in the same anatomical sites.

The YC-200 is substantially equivalent to the primary predicate device in principles of operation, technological characteristics, and performance. Any differences in technological characteristics among the subject device, and primary predicate device do not raise any new issues of safety or effectiveness. Thus, the YC-200 is substantially equivalent to the primary predicate device.

TESTING IN SUPPORT OF A SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the OPHTHALMIC YAG LASER SYSTEM YC-200 to support a determination of substantial equivalence to the predicate and reference devices. The tests performed include:

- Ophthalmic Testing per ISO15004-1
- Testing for Protection against Light Hazard per Z80.36 and ISO15004-2
- Slit Lamp Testing per ANSI Z80.37
- Laser Product Safety Testing per IEC 60601-2-22 and IEC 60825-1
- Usability Testing per IEC 62366-1
- Electrical Safety Testing per ANSI AAMI ES60601-1 and Electromagnetic Compatibility Testing per IEC60601-1-2.
- Risk management per ISO14971

The collective performance testing demonstrates that the YC-200 does not raise any new questions of safety or effectiveness when compared to the primary predicate device. The results of the performance testing demonstrate that the YC-200 performs as intended and does not raise any new questions of safety or effectiveness.

SUMMARY

The OPHTHALMIC YAG LASER SYSTEM YC-200 is substantially equivalent to the primary predicate device.