DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 23, 2017

Nidek Incorporated
Toshio Murata
Senior RA/QA Manager
47651 Westinghouse Drive
Fremont, CA 94539

Re: K170302
Trade/Device Name: Yellow Laser Photocoagulator System YLC-500
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: May 31, 2017
Received: June 1, 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 yours,

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)*

K170302

Device Name

YELLOW LASER PHOTOCOAGULATOR SYSTEM YLC-500

Indications for Use *(Describe)*

The YELLOW LASER PHOTOCOAGULATOR SYSTEM YLC-500 is intended to be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty. The YELLOW LASER PHOTOCOAGULATOR SYSTEM YLC-500 is intended to work in conjunction with the following delivery units in ophthalmic photocoagulation procedures: NIDEK SL-1800, SL-1600, ZEISS SL 130, HAAG BQ900, HEINE OMEGA 500

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(K) SUMMARY

GENERAL INFORMATION

Submission K170302

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Date Prepared: January 30, 2017

DEVICE INFORMATION

Trade Name:

Yellow Laser Photocoagulator System YLC-500

Generic/Common Name:

Ophthalmic laser

Classification:

21 CFR §886.4390, Class II

Product Code:

HQF

PREDICATE DEVICE(S)

- GREEN LASER PHOTOCOAGULATOR MODEL GYC-500 (K152603) (as the primary predicate device with indications for use and technological characteristics that are most similar to the YLC-500)
- MULTICOLOR SCAN LASER PHOTOCOAGULATOR MC-500 Vixi (K111493)

The GYC-500 is chosen as the primary predicate device because it has the similar indications for use as and technological characteristics to the YLC-500. The hardware and software structures are similar between the YLC-500 and GYC-500 although the YLC-500 emits the treatment laser of a different wavelength with the different power output range from the GYC-500.

The MC-500 Vixi is also necessary and appropriate to support substantial equivalence in wavelength of and power output range of the treatment laser to the YLC-500.

INDICATIONS FOR USE

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

The Yellow Laser Photocoagulator System YLC-500 is intended to work in conjunction with the following delivery units in ophthalmic photocoagulation procedures: NIDEK SL-1800, SL-1600, ZEISS SL 130, HAAG BQ900, HEINE OMEGA 500

PRODUCT DESCRIPTION

The Yellow Laser Photocoagulator System YLC-500 (hereafter referred to as "YLC-500") is a laser photocoagulator for ophthalmology using the 577 nm optically-pumped semiconductor laser (yellow laser beam) as the treatment beam and 635 nm diode laser (red laser beam) as the aiming beam. Like other conventional laser photocoagulation systems, the YLC-500 can be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty. The YLC-500 is a modified version of the GYC-500 as the primary predicate device and MC-500 Vixi which were the subjects of premarket notification numbers K152603 and K111493.

The YLC-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 YLC-500, the operator sets laser emission conditions such as laser power output, spot size, and exposure time according to the condition of treatment site through the control box of the YLC-500 or operation part of the connected delivery unit. When using an (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 YLC-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 operator 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 scanning manner when a scan (attachable) delivery unit is connected to the YLC-500.
Various types of the delivery units are available for the YLC-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.

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 YLC-500 connected with a scan (attachable) delivery unit is called “Yellow Scan Laser Photocoagulator YLC-500 Vixi”.

Various slit lamp delivery units are available that allow for the adaptation of the YLC-500 to a slit lamp. An optical fiber cable is connected from the YLC-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 delivery units 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), and Scan attachable delivery unit (NIDEK SL-1800/SL-1600 type, ZEISS SL 130 type, HAAG BQ900).

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

The B.I.O. delivery unit enables photocoagulation using a yellow laser beam (577 nm) while observing the patient’s eye with a binocular indirect ophthalmoscope. With the delivery unit, the patient can be treated in a supine position. The delivery unit (Heine Omega 500 type) connects to the YLC-500 main body via an optical fiber cable. The 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 distance among the operator, the patient, and 20 D condensing lens, which can be varied within a range of 300 to 700 mm. The treatment and aiming beam spot size can also be selected by changing working distance (with the 20D condensing lens).

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.

Comparison of technological characteristics with predicate devices

The YLC-500 and the predicate devices are all laser photocoagulators that are intended for use in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty. The YLC-500 and MC-500 Vixi emit a continuous optically-pumped semiconductor laser of 577 nm, whereas the MC-500 Vixi emits the lasers of 532 nm and that of 647 nm as well. The YLC-500's main body, control box and expansion box have three CPUs that are identical to the GYC-500 to respectively control the main body, control box and expansion box. The YLC-500 uses the expansion box controlling the scan function in common with the GYC-500 that was previously cleared in 510(k) No.152603. The YLC-500 uses the same cooling method as the predicate devices.

With regard to the specifications for the laser beams emitted from the YLC-500, the range of power output of the treatment laser is the same as that of 577 nm treatment laser of the MC-500 Vixi. The range of the exposure time, and the specifications for the aiming beam including the range of aiming beam power output available with the YLC-500 are the same as those of the GYC-500.

The YLC-500 is connected to one (or two when the dual type is used) of various types of delivery units to deliver the treatment laser beam to the patient's eye. The connected (scan/attachable) slit lamp delivery units are the same between the YLC-500 and GYC-500 except for the cutoff wavelength as discussed in "Justification that differences do not affect safety and effectiveness" of Table 12.1 "Substantial equivalence comparison table for YLC-500 and the predicate devices". The cutoff wavelength of the protective filter is the same between the (scan/attachable) slit lamp delivery units for the YLC-500 and those for the MC-500 Vixi. All the (scan/attachable) delivery units have the same intended use, principles of operation and technological characteristics as the delivery units connectable to the predicate devices, and also, the laser output emitted from these delivery units was tested and found to comply with IEC60601-2-22 and IEC 60825-1.

The YLC-500 also provides the operator with the option of performing procedures by delivering the laser beam in either a single spot or in patterns as the predicate devices do. Specifically, the YLC-500 and MC-500Vixi allow the operator to deliver a single spot laser or patterned scanning laser of 577 nm when connected to a scan (attachable) slit lamp delivery unit, whereas the MC-500 Vixi delivers a single spot or patterned scanning laser in three different wavelengths (i.e., green, yellow, and red) as well. The scan patterns available with the YLC-500 are the same as those with the GYC-500. CPU-controlled scanning mirrors create the various scan patterns consistently by moving the scanning mirrors and by deflecting the laser beam. The movable range of the scanning mirrors and the way the mirrors are driven, and control circuit are the same between the YLC-500 and predicate devices.

Comparison of technological characteristics with predicate devices is provided in Table 1:

Table 1 Substantial equivalence comparison table for YLC-500 and the predicate devices

Product	Yellow Laser Photocoagulator System YLC-500	Multicolor Scan Laser Photocoagulator MC-500 Vixi	Green Laser Photocoagulator GYC-500
Manufacturer	NIDEK	NIDEK	NIDEK
510(k) number	—	K111493	K152603
510(k) clearance date	—	07/27/2011	05/02/2016
Regulation medical specialty	Ophthalmic	←	←
Review panel	Ophthalmic	←	←
Product code	HQF	←	←
Regulation number	21 CFR 886.4390	←	←
Regulation description	Ophthalmic laser	←	←
Classification	II	←	←
Indications for use	The Yellow Laser Photocoagulator System YLC-500 is intended to be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and	The NIDEK Multicolor Scan Laser Photocoagulator MC-500 Vixi is intended to be used in ophthalmic surgical procedures, including retinal and macular photogoatulation, iri-	The NIDEK Green Laser Photocoagulator GYC-500 is intended to be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and

Product	Yellow Laser Photocoagulator System YLC-500	Multicolor Scan Laser Photocoagulator MC-500 Vixi	Green Laser Photocoagulator GYC-500
	trabeculoplasty. The Yellow Laser Photocoagulator System YLC-500 is intended to work in conjunction with the following delivery units in ophthalmic photocoagulation procedures: NIDEK SL-1800, SL-1600, ZEISS SL 130, HAAG BQ900, HEINE OMEGA 500	dotomy and trabeculoplasty.	trabeculoplasty.
Application	Ophthalmology	←	←
Technical specifications			
Treatment laser			
Laser type	Optically-pumped semiconductor laser	532 nm: Diode-pumped solid-state laser, 577 nm: Optically-pumped semiconductor laser, 647 nm: Diode laser	Diode-pumped solid-state laser
Wavelength	577 nm	532 nm 577 nm 647 nm	532 nm
Laser mode	Continuous wave	←	←
Power output	50 to 1500 mW (50 to 500 mW in increments of 10mW, 500 to 1500 mW in increments of 50mW) 50 to 1500 mW (Scan Mode)	532 nm: 50 to 1700 mW, 50 to 1500 mW (Scan Mode) 577nm: 50 to 1500 mW 647nm: 50 to 800 mW	50 to 1700 mW (50 to 500 mW in increments of 10mW, 500 to 1700 mW in increments of 50mW) 50 to 1500 mW (Scan Mode)
Exposure time	Single spot: 0.01 to 3.00 sec. Scan Mode: 0.01 to 0.05 sec. Auto M Mode 0.01 to 3.00 sec	Single spot: 0.01 to 1.00 sec, 2.00 sec. and 3.00 sec. Scan Mode: Pattern: 0.01 to 0.03 sec., Auto M Mode Single spot: 0.01 to 1.00 sec., 2.00 sec. and	Single spot: 0.01 to 1.00, 2.00, 3.00 sec 0.01 to 0.10 sec: 0.01 increments 0.10 to 0.50 sec: 0.05 increments 0.50 to 1.00 sec: 0.1 increments

Product	Yellow Laser Photo-coagulator System YLC-500	Multicolor Scan Laser Photocoagulator MC-500 Vixi	Green Laser Photo-coagulator GYC-500
		3.00 sec.	Scan Mode Pattern: 0.01 to 0.05 sec. Auto M Mode Single spot: 0.01 to 1.00 sec., 2.00 sec. and 3.00 sec.
Interval time	0.05 to 1.0 sec	0.05 to 1.0 sec. in 0.05 increments	0.05 to 1.0 sec. in 0.05 increments
Cooling Method	Air cooled	←	←
Aiming beam			
Type	Laser diode	←	←
Wavelength	635 nm	670 nm	635 nm
Laser mode	Continuous wave	←	←
Power output	0.3±0.1 mW	0.4 to 0.8 mW	0.2 to 0.4 mW
Delivery units			
Slit Lamp Delivery Unit	• NIDEK SL-1800	• NIDEK SL-1800	• NIDEK SL-1800
Attachable slit lamp delivery unit	• For ZEISS SL-130 • For NIDEK SL-1800/SL-1600	• For ZEISS 30SL/M • For NIDEK SL-1800	• For ZEISS 30SL/M, • For ZEISS SL130, • For NIDEK SL-1800/SL-1600 • For HAAG 900BM /900BQ
Scan slit lamp delivery unit	• NIDEK SL-1800	• NIDEK SL-1800	• NIDEK SL-1800
Scan attachable slit lamp delivery unit	• For NIDEK SL-1800/1600 • For Zeiss SL 130 • For HAAG BQ900	•For Zeiss 30SL/M, • For NIDEL SL-1800, • For Zeiss SL 130	• For ZEISS 30SL/M, • For NIDEK SL-1800/SL-1600 • For ZEISS SL130, • For HAAG 900BQ
Binocular Indirect Ophthalmoscope (B.I.O.) delivery unit	HEINE OMEGA 500	HEINE OMEGA 500	HEINE OMEGA 500, KEELER All Pupil II
Scan patterns	Single, Square (2×2, 3×3, 4×4, 5×5), Equal Space (2v2, 3v3, 4v4, 5v5) *1, Line, Triangle, Curve, Circle, Arc (3/4 circle, 2/4 circle, 1/4	Single spot, Squire (2×2, 3×3, 4×4, 5×5) Circle, Arc, Triple Arc, Macula Grid, Triangle, Line, and Curve	Single spot, Squire (2×2, 3×3, 4×4, 5×5), Equal space (2v2, 3v3, 4v4, 5v5), Line, Triangle, Curve, Circle, Arc (3/4 circle, 1/2 circle,

Product	Yellow Laser Photo-coagulator System YLC-500	Multicolor Scan Laser Photocoagulator MC-500 Vixi	Green Laser Photo-coagulator GYC-500
	circle), Triple Arc, Arcade Grid, Rectangle, Triple Curve		1/4 circle), Triple Arc, Arcade Grid (Arcade Grid, Arcade Grid 1, Arcade Grid 2), Rec-tangle, Triple Curve
Spot size	Slit lamp delivery unit: 50 to **990 µm** Scan slit lamp delivery unit: 50 to 500 µm, 100 to 500 µm in scan mode B.I.O. delivery: 212 to 664 µm	Slit lamp delivery unit: 50 to 1000 µm, Scan slit lamp delivery unit: 50 to 500 µm in single mode, 100 to 500 µm in scan mode B.I.O. delivery: HEINE OMEGA 500 212 to 664 µm, Combination delivery: 50 to 500 µm	Slit lamp delivery unit: 50 to 1000 µm Scan slit lamp delivery: 50 to 500 µm in single mode, 100 to 500 µm in scan mode B.I.O. delivery HEINE OMEGA500: 212 to 664 µm KEELER AP II: 185 to 556 µm Combination delivery: 50 to 500 µm
Guard wave-length of pro-tective filter	577 nm	532 nm, 577 nm, 647 nm	532 nm
Electrical re-quirements			
Voltage	100 to 240 VAC ±10% 50/60 Hz ±1 Hz	100 to 240 VAC ±10% 50/60 Hz	100 to 240 Vac 50/60 Hz
Power con-sumption	250 VA	400 VA or less	250 VA
Physical char-acteristics			
Dimension	237 (W) × 318 (D) × 90 (H) mm (excluding protrusions)	670 × 480 × 300 mm	237 (W)× 318 (D) × 90 (H) mm
Weight	5.6 kg	**35 kg**	**6.2 kg** (excluding the control box)

SUBSTANTIAL EQUIVALENCE

The YLC-500 is substantially equivalent to the predicate devices, Green Laser Photocoagulator Model GYC-500 as the primary predicate device, and Multicolor Scan Laser Photocoagulator MC-500 Vixi. They are all laser photocoagulators that are intended for use in ophthalmic

surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty..

The YLC-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 YLC-500 is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the Yellow Laser Photocoagulator System YLC-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 per AAMI/ANSI/IEC 62304
  The software of this device was considered as a "Major" level of concern based on the FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* issued on: May 11, 2005.
- 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 YLC-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 YLC-500 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 Yellow Laser Photocoagulator System YLC-500 does not introduce any new potential safety risks, is as effective and performs as well as the predicate devices, and concludes that the YLC-500 is substantially equivalent to the predicate devices.

SUMMARY

The Yellow Laser Photocoagulator System YLC-500 is substantially equivalent to the predicate devices.