May 3, 2019

Norlase ApS
% Sheila Pickering
Consultant
Sheila Pickering Consulting Group
2081 Longden Circle
Los Altos, CA 94024

Re: K190083
Trade/Device Name: Leaf Photocoagulator
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: January 16, 2019
Received: February 04, 2019

Dear Sheila Pickering:

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 and Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Malvina B. Eydelman, M.D.
Director
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. 09100120 Expiration Date: January 31, 2017 See PRA Statement below.

510(k) Number (if known)

K190083

Device Name Norlase Leaf Photocoagulator

Indications for Use (Describe)

The Norlase Leaf Photocoagulator is intended to be used in ophthalmic laser 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)

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)

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

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510(k) Summary
Prepared January 16, 2019

Sponsor: Norlase ApS
Brydehusvej 30
2750 Ballerup
Denmark

Contact Person: Jan Forstberg

Telephone: +4593977472

Submission Date: January 16, 2019

Device Name: Leaf Photocoagulator

Common Name: Photocoagulator

Classification:
Regulatory Class: II
Review Category: Ophthalomology Photocoagulator
21CFR 886.4390 (HQF)
Classification Panel: Ophthalmology

A. Legally Marketed Predicate Devices

The predicate device is the NIDEK Green Laser Photocoagulator GYC-500 ("NIDEK"). (K152603)

B. Device Description:

The Norlase Leaf device consists of a laser unit, a wireless control unit and a foot switch. The laser unit must be attached to the Doctors own compatible slit lamp to work as a full system. The Norlase Leaf Device is controlled by the wireless control unit that allows the Doctor to set the desired parameters for treatment. A shrouded foot switch is connected to the laser unit to control the emission of laser light.
The Doctor will use the user supplied slit lamp to identify the area to be treated and after setting the appropriate parameters, will target the ophthalmic tissue utilizing a visible red aiming laser. The foot switch will be pressed by the Doctor to deliver therapeutic green laser light to the target tissue. A mechanically fixed eye safety filter is built into the Laser Unit to protect the Doctor from any stray or reflected green laser light travelling along the visual path of the slit lamp.
The Norlase Leaf device consists of the following modules:

- Laser unit + power supply + power cable
- Foot switch + cable
- Control unit (Tablet computer with installed Software) + power supply + USB cable

The wavelength of the treatment beam is centered around ~520 nm, and the maximum optical output power is 1.5W (to tissue). The laser is operated in continuous wave (CW) mode and electronically pulsing the laser output power to achieve durations from 50 µsec to 1 second. Laser parameters are controlled by a Control Unit (tablet) User Interface that utilizes a touchscreen control to select or change a setting. Voice Control of selected parameters is an optional feature that can assist in the increment or selection of a parameter,

C. Intended Use

The Leaf Photocoagulator is intended to be used in ophthalmic laser procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

D. Substantial Equivalence

Device Name	**Norlase LEAF green laser photocoagulator**	**Green Laser Photocoagulator GYC-500**	**Substantially Equivalent**
Manufacturer	Norlase	Nidek	N/A
510(k) number	-	K152603	N/A
510(k) clearance date	-	05/02/2016	N/A
Review panel	Ophthalmic	Ophthalmic	YES
Product code	HQF	HQF	YES
Regulation number	886.4390	886.4390	YES
Regulation description	Ophthalmic laser	Ophthalmic laser	YES
Classification	II	II	YES
Indication for use and Intended use	The Norlase Leaf Photocoagulator is intended to be used in ophthalmic laser procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty.	The NIDEK Green Laser Photocoagulator GYC-500 is intended to be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty.	YES
User interface	Manual and voice control	Manual	YES
Connectivity	Wireless	Hard wired	YES
Laser type	Laser diode	Diode-Pumped Solid-State laser	YES
Wavelength	520 nm	532 nm	YES
Laser mode	Continuous wave	Continuous wave	YES
Power output	50 to 1500 mW	50 to 1700 mW	YES
Exposure time (Duration time)	0.05 ms to 1 s	0.01 s to 3 s	YES
Interval time	50 ms to 3 s	50 ms to 1 s	YES
Cooling method	Air cooled	Air cooled	YES
Aiming beam:			
Type	Laser diode	Laser diode	YES
Wavelength	635 nm	635 nm	YES
Laser mode	Continuous wave	Continuous wave	YES
Power output	<1 mW (adjustable)	<0.4 mW (adjustable)	YES
Voltage	100 to 240 Vac 50/60 Hz	100 to 240 Vac 50/60 Hz	YES
Power consumption	120 VA	250 VA	YES
Dimension	253 (H) x 153 (W) x 43 (D) mm	237 (W) x 318 (D) x 90 (H) mm	YES
Weight	~1.5 kg (excluding control unit, foot switch and power supply)	6.2 kg (excluding the control box)	YES

In summary based on the comparison of indications for use and technological characteristics of the subject device is substantially equivalent to the predicate. Based on the performance data provided in the submission these differences do not introduce new issues related to safety and efficacy.

E. Performance Data

Every specification of the Leaf Photocoagulator device has been verified and validated according to the company's documented development and test procedures. The verification and validation testing included testing to the following applicable standards:

ISO 14971	Application of risk management to medical devices
ISO 15004-2	Ophthalmic instruments - Fundamental requirements and test methods - Part 1: Light hazard protection
IEC 60601-1+	Medical electrical equipment- General requirements for basic safety and essential performance
IEC 60601-1-2	Electromagnetic disturbances
IEC 60601-2-22	Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
IEC 60825-1	Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]11
IEC 62304+	Medical device software - Software life-cycle processes
IEC 62366-1	Application of usability engineering to medical devices
ANSI Z136-1	American National Standard for Safe Use of Lasers
ANSI Z136-3	American National Standard for Safe Use of Lasers in Health Care

Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30. Successful results for the following tests were included in the submission as performance data supporting substantial equivalence:

1. Bench testing for electrical and mechanical safety in compliance with the laser standards cited above
2. Bench testing for laser performance in compliance with the laser standards cited above
3. Bench testing specific to ophthalmic devices in compliance with the standard cited above

4. Software testing, consisted of verification and validation testing in compliance with ISO 62304, including test cases related to off the shelf software as well as cybersecurity features
5. Human factors testing to demonstrate usability in a simulated use environment when used by health care professionals

Clinical data was not required for this type of device.

F. Conclusion

Potential risks were identified according to the ISO 14971 Standard. The risks were analyzed with regard to risk/benefit category and mitigations were implemented and tested as part of the performance testing described above. All risk mitigations were satisfactorily verified and validated. Where there were technological differences from the predicate, these were shown not to result in any new issues of safety or efficacy according to the performance data submitted.

Therefore, the Leaf Photocoagulator is substantially equivalent to the predicate device with regards to intended use and technological characteristics. Results of performance testing demonstrated that the device met the design requirements and as well as the user needs