October 11, 2022

Norlase
Jan Forstberg
Vice President of Regulatory Affairs and Quality Assurance
Brydehusvej 13
Ballerup, Hovedstaden DK-2750
Denmark

Re: K222157
Trade/Device Name: ECHO Photocoagulator
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: July 15, 2022
Received: July 20, 2022

Dear Jan Forstberg:

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,

Anjana Jain, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222157

Device Name
ECHO Photocoagulator

Indications for Use *(Describe)*

The Norlase ECHO 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary - K222157
Prepared September 16, 2022

Sponsor: Norlase ApS
Brydehusvej 13
2750 Ballerup
Denmark

Contact Person: Jan Forstberg

Telephone: + 45-40-109302

Submission Date: September 16, 2022

Device Name: ECHO Photocoagulator

Common Name: Photocoagulator

Classification:

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

A. Legally Marketed Predicate Devices

The predicate device is the Norlase Leaf Photocoagulator (K190083) also classified according to 21CFR 886.4390 (HQF).

B. Device Description:

The Norlase ECHO device is a modification to the Norlase Leaf Photocoagulator (K190083) and also 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 ECHO 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 Echo 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. The ECHO modification consists of capability for pattern scanning.

C. Intended Use

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

D. Substantial Equivalence

Device Name	**Primary Predicate Device Norlase LEAF green laser photocoagulator K190083**	**Subject Device Norlase ECHO green laser photocoagulator**	**Substantial Equivalence**
Manufacturer	Norlase	Norlase	Identical
510(k) number	K190083	K222157	N/A
510(k) decision date	05/03/2019	N/A	N/A
Regulation medical specialty	Ophthalmic	Ophthalmic	Identical
Review panel	Ophthalmic	Ophthalmic	Identical
Product code	HQF	HQF	Identical
Regulation number	886.4390	886.4390	Identical
Regulation description	Ophthalmic photocoagulator	Ophthalmic photocoagulator	Identical
Classification	2	2	Identical
Indication for use and Intended use	The Norlase LEAF Photocoagulator is intended to be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty	The Norlase ECHO Photocoagulator is intended to be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty.	Identical
User interface	Manual and voice control	Manual and voice control	Identical
Connectivity	Wireless	Wireless	Identical
Treatment Beam			
Laser type	Laser diode	Laser diode	Identical
Wavelength	520 nm	520 nm	Identical
Laser mode	Continuous wave (CW)	Continuous wave (CW)	Identical
Power output	50 to 1500 mW	50 – 1500 mW	Identical
Exposure time	0.05 ms to 1 s.	0.05 ms to 1 s.	Identical
Interval time	50msec-3sec	50msec-3sec	Identical
Cooling method	Air cooled	Air cooled	Identical
Single spot	Yes	Yes	Identical
Pattern scanning	No	Yes	Similar

Pulse counter	0 – 9,999	0 – 9,999	Identical
Laser beam diameter at focus	50, 100, 200, 300, and 500 µm	50, 100, 200, 300, and 500 µm	Identical
Other specifications:			
Attachable slit lamp delivery unit	For HAAG 900BM/900BQ and similar Zeiss 30SL, SL130 and similar	For HAAG 900BM/900BQ and similar Zeiss 30SL, SL130 and similar	Identical
Spot size	50 to 500 µm	50 to 500 µm	Identical
Voltage	100 to 240 Vac 50/60 Hz	100 to 240 Vac 50/60 Hz	Identical
Power consumption	120 VA	120 VA	Identical
Dimension	253 (H) x 153 (W) x 43 (D) mm	253 (H) x 153 (W) x 43 (D) mm	Identical
Weight	4 kg	4 kg	Identical

In summary, based on the comparison of indications for use and technological characteristics of the subject device is substantially equivalent to the predicate device. 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 ECHO 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 electrical safety and 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. Bench testing for verification and validation of the specified performance of the pattern scanning feature for the subject device.
5. 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 and the software used to implement the patten scanning feature for the subject device.
6. Human factors evaluation to demonstrate usability in a simulated use environment when used by health care professionals

To address the added capability for pattern scanning, an additional comparison was provided to a reference device, the Topcon PASCAL Synthesis TwinStar Ophthalmic Scanning Laser System (K170409).

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 ECHO 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