February 10, 2021

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

Re: K201623
Trade/Device Name: Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF, GEX

Dear Sheila Pickering:

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 sent August 11, 2020. Specifically, FDA is updating this SE Letter because the original letter sent was missing the date of clearance. This is an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact LT Charles Chiang, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6459, Charles.Chiang@fda.hhs.gov.

Sincerely,

Charles Chiang -S

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

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Re: K201623
Trade/Device Name: Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF, GEX
Dated: July 6, 2020
Received: July 13, 2020

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); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201623

Device Name
Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator

Indications for Use *(Describe)*

The Norlase Laser Indirect Ophthalmoscope (LIO) 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.

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.

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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) Summary K201623
Prepared June 12, 2020

Sponsor: Norlase ApS
Brydehusvej 30
2750 Ballerup
Denmark

Contact Person: Jan Forstberg

Telephone: +4593977472

Submission Date: June 12, 2020

Device Name: Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator

Common Name: Photocoagulator

Trade Name: Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator

Classification:

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

A. Legally Marketed Predicate Devices

The primary predicate device is the Norlase LEAF Green Laser Photocoagulator (K190083).
The reference predicate is the Iridex TruFocus LIO (K170718).

B. Device Description:

The Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator system was developed to utilize advancements in visible green semiconductor (diode) laser technology and to provide a compact design to be incorporated in a lightweight headset worn by the physician. The Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator system consists of an indirect ophthalmoscope headpiece, a headset laser enclosure/casing, a wireless user interface tablet, a footswitch with a battery, and a cable extending from the footswitch to the headset.
The Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator system is controlled by the wireless user interface tablet that allows the physician to set the desired parameters for treatment. A shrouded footswitch is connected to the headset to control the emission of laser light and the battery to power the device illumination and laser source. The physician uses the headset to locate the area to be treated and after setting the appropriate parameters, targets the desired tissue

utilizing a visible red aiming beam. The foot switch is pressed by the physician to deliver therapeutic green laser light to the targeted tissue. Eye safety filters are built into the laser unit to protect the physician's eyes while providing a clear view of the target area.

C. Intended Use / Indications for Use

The Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator is intended to be used in ophthalmic laser procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

D. Substantial Equivalence

The Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator system is substantially equivalent to the original device, the Norlase Leaf Green Laser Photocoagulator cleared per K190083, as well as the Iridex TruFocus LIO (K170718) They are both laser photocoagulators for the purpose of Ophthalmology treatment. The indications for use and the core technology of the primary Norlase predicate have not changed. The core difference is the change of device configuration from a stationary slit lamp mounted device to a headset mounted LIO configuration. The reference predicate has a broader indication for use for multiple applications but has substantially equivalent technological characteristics.

Device Name	**Primary Predicate Norlase LEAF Photocoagulator K190083**	**Reference Predicate Iridex TruFocus LIO K170718**	**Subject Device Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator**	**SE**
Indications for Use	Intended to be used in ophthalmic laser procedures including retinal and macular photocoagulation, iridotomy, and trabeculoplasty.	The Iridex TruFocus LIO Premiere Laser Indirect Ophthalmoscope with the Family of Iridex® IQ Laser Systems is intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of, dermatology, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology	Intended to be used in ophthalmic laser procedures including retinal and macular photocoagulation, iridotomy, and trabeculoplasty.	Yes
Manufacturer	Norlase	Iridex Corp.	Norlase	N/A
510(k) number	K190083	K170718	TBD	N/A
Regulation medical specialty	Ophthalmic	General and Plastic Surgery	Ophthalmic	YES
Review panel	Ophthalmic	Ophthalmic	Ophthalmic	YES
Product code	HQF	GEX	HQF	YES

Regulation number	886.4390	878.4810	886.4390	YES
Regulation description	Ophthalmic photocoagulator	Ophthalmic photocoagulator	Ophthalmic photocoagulator	YES
Classification	II	II	II	YES
Treatment beam				
Laser type	Laser diode	Laser diode	Laser diode	YES
Wavelength	520 nm	532mm	520 nm	YES
Laser mode	Continuous wave	Continuous wave	Continuous wave	YES

Based on the comparison of indications for use and technological characteristics, the subject device is substantially equivalent to the primary predicate device as well as the reference predicate. Based on the performance data provided in the submission the differences do not introduce new issues related to safety and efficacy.

E. Performance Data

Every specification of the Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator system has been verified and validated as required by the risk analysis. All design verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

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. Norlase certifies that all verification and validation activities provided in this submission were performed by designated individuals and

results demonstrate that predetermined acceptance criteria were met. 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 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 and ISO 62366 Standards. 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 predicates, these were shown not to result in any new issues of safety or efficacy according to the performance data submitted.

Therefore, the Norlase Laser Indirect Ophthalmoscope (LIO) Photocoagulator is substantially equivalent to the predicate devices 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.