March 13, 2025

G.N.S neoLaser Ltd.
Gil Shapira
CEO
Ha'Eshel St. 7
Caesarea, 3088900
Israel

Re: K250113
Trade/Device Name: neoLaser Laser Surgery Fibers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: January 8, 2025
Received: January 16, 2025

Dear Gil Shapira:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.03.13 17:18:32 -04'00'

for Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250113

Device Name
neoLaser Laser Surgery Fibers

Indications for Use *(Describe)*
The Fibers are indicated for use in general surgical applications for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue. It is also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated. The neoLaser Laser Surgery Fibers have a wavelength range of 450 nm to 2100 nm, can be used in contact and non-contact mode and are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT and endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis with a cleared compatible laser marketed for the mentioned intended uses and using an SMA 905 connector.

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."

7 HaEshel St., Caesarea 3088900, ISRAEL | Tel: +972 4 6779919 | Fax: +972 4 8591505
info@neo-laser.com | www.neo-laser.com

K250113 - neoLaser Laser Surgery Fibers – Traditional Submission - 510(k) Summary

Submitter:
G.N.S neoLaser Ltd. (neoLaser)
7 HaEshel St.
Caesarea 3088900
Israel

Contact person: Gil Shapira, CEO
Phone: +972 4 6779919
Fax : + 972 4 8591505
e-Mail: shapirag@neo-laser.com

Type of 510(k) Traditional

Date Prepared: January 8, 2025

Device Trade Name: neoLaser Laser Surgery Fibers

Common Name: Fiber optic laser delivery system

Classification Name: General and Plastic Surgery

Device product code: GEX

Device Classification: 21 CFR 878.4810

Predicate: BeaMed Laser Surgery Fibers (K232769)

Device Description:
The neoLaser Laser Surgery Fibers are sterile, single use, laser delivery devices intended for medical applications in various fields of laser surgery. They are intended to deliver energy to soft tissue in contact and non-contact mode during various surgical applications, including via endoscopes and cytoscopes. The fibers are designed to transmit energy from the laser system to the treatment site, as well as to transmit a low power laser aiming beam to assist in the visibilty of the target tissue.

7 HaEshel St., Caesarea 3088900, ISRAEL | Tel: +972 4 6779919 | Fax: +972 4 8591505
info@neo-laser.com | www.neo-laser.com

Indications for Use:
The Fibers are indicated for use in general surgical applications for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue. It is also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated.

The neoLaser Laser Surgery Fibers have a wavelength range of 450 nm to 2100 nm, can be used in contact and non-contact mode and are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT and endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis with a cleared compatible laser marketed for the mentioned intended uses and using an SMA 905 connector.

Comparison between subject and predicate devices

Specification	**Subject Device** **neoLaser Laser Surgery Fibers**	**Predicate Device** **BeaMed Laser Surgery Fibers**
510(k)	Pending	K232769
Indications for Use	The Fibers are indicated for use in general surgical applications for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue. It is also indicated for use in open or closed endoscopic applications where incision, excision,tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated. The neoLaser Laser Surgery Fibers have a wavelength range of 450 nm to 2100 nm, can be used in contact and non-contact mode and are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT and endovenous occlusion of the greater saphenous	The Fibers are indicated for use in general surgical applications for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue. It is also indicated for use in open or closed endoscopic applications where incision, excision,tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated. The BeaMed Laser Surgery Fibers have a wavelength range of 450 nm to 2100 nm, can be used in contact and non-contact mode and are indicated for use in general surgery, urology, gastroenterology, gynecology,

	vein in the patient with superficial vein reflux and laser assisted lipolysis with a cleared compatible laser marketed for the mentioned intended uses and using an SMA 905 connector.	dermatology, vascular surgery, neurosurgery, plastic surgery, ENT and endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis with a cleared compatible laser marketed for the mentioned intended uses and using an SMA 905 connector.
Fiber core material	Silica quartz glass	Silica quartz glass
Fiber cladding material	silica quartz glass cladding and/or Hardclad (depending on type of fiber)	silica quartz glass cladding and/or Hardclad (depending on type of fiber)
Buffer	silicone buffer (depending on type of fiber)	silicone buffer (depending on type of fiber)
Jacket material	silicone / ETFE /polymide /nylon / acrylate / PVDF/ PU may be used in the jacket depending on type of fiber. Color additives (see Biocompatibility tests) may be included according to fibers models and variants.	silicone / ETFE /polymide /nylon / acrylate / PVDF/ PU may be used in the jacket depending on type of fiber. Color additives (see Biocompatibility tests) may be included according to fibers models and variants.
Maximal temperature	176ºF (80ºC) for nylon jacket, 302ºF (150ºC) for ETFE jacket	176ºF (80ºC) for nylon jacket, 302ºF (150ºC) for ETFE jacket
Minimal bend radius	51 x core diameter (short term) 121 x core diameter (long term)	51 x core diameter (short term) 121 x core diameter (long term)
Maximal laser power	Suitable for laser power up to 100W	Suitable for laser power up to 100W
Shelf life	5 years	5 years
Numerical aperture range	0.37 (for quartz/ hardclad fibers), 0.22 (for quartz /quartz)	0.37 (for quartz/ hardclad fibers), 0.22 (for quartz /quartz)
Core diameter range	200 µm to 1000 µm	200 µm to 1000 µm
Outer diameter range	240 µm to 1800 µm typically	240 µm to 1800 µm typically
Distal fiber tip types	Flat, conical, ball, spherical or bended bare fibers, round or conical caps	Flat, conical, ball, spherical or bended bare fibers, round or conical caps
Fiber tip outer diameter range	1.0mm to 1.8mm	1.0mm to 1.8mm

7 HaEshel St., Caesarea 3088900, ISRAEL | Tel: +972 4 6779919 | Fax: +972 4 8591505
info@neo-laser.com | www.neo-laser.com

Specification	Subject Device neoLaser Laser Surgery Fibers	Predicate Device BeaMed Laser Surgery Fibers
Wavelength range	450nm to 2100 nm	450nm to 2100 nm
Length range	6.5 feet (2 meters) to 9.9 feet (3 meters)	6.5 feet (2 meters) to 9.9 feet (3 meters)
Emission angle range	Straight, forward directed cone or 60º cone angle from fiber axis, diffuse emission, and radial 360º	Straight, forward directed cone or 60º cone angle from fiber axis, diffuse emission, and radial emission of 360º
Single/multiple use	Single use	Single use
Sterility	Sterile by EO	Sterile by EO
Packaging	Sterile, double pouched	Sterile, double pouched
Proximal end	SMA 905 connector	SMA 905 connector

Summary of performance bench testing included in the submission:
Packaging seal strength
Dye penetration test
Packaging microbial barrier
Shelf-life validation summary
Sterilization process validation plan
Sterilization process validation protocol
Sterilization process validation report
Sterility Assurance Level (SAL)
EO-ECH residuals report
LAL Endotoxin test
Bioburden bare fibers test / Bioburden capped fibers tests
Biocompatibility tests protocols & reports
Thermal safety validation

Substantial Equivalence summary and conclusion
The neoLaser Laser Surgery Fibers and the predicate device, the BeaMed Laser Surgery Fibers (K232769) share the same indications for use, the same technical and performance characteristics, accordingly, the safety and effectiveness of the neoLaser Laser Surgery Fibers is based upon a determination of the substantial equivalence to the predicate device.

Conclusion and substantial equivalence statement
After our analysis we have concluded that the subject device neoLaser Laser Surgery Fibers, and the predicate device the BeaMed Laser Surgery Fibers, share the same technical characteristics and the same intended use.
Accordingly, we believe that the neoLaser Laser Surgery Fibers and the legally marketed predicate, the BeaMed Laser Surgery Fibers (K232769), are substantially equivalent.
Animal or clinical studies: **None**