December 21, 2024

Light Guide Optics International Ltd.
Santa Vucina
Official Correspondent
Celtniecibas Street 8
Livani, LV-5316
Latvia

Re: K243147
Trade/Device Name: LGO-Surgical Laser 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: September 30, 2024
Received: September 30, 2024

Dear Santa Vucina:

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: 2024.12.21 10:13:33 -05'00'

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)*
K243147

Device Name
LGO-Surgical Laser Fibers

Indications for Use *(Describe)*
LGO-Surgical Laser Fibers are intended to be used to deliver the laser radiation to the target tissue when used with any cleared/certified laser with operational wavelengths between 500 nm - 2200 nm equipped with SMA 905 standard or freestanding ferrule connector, as per the indications of the laser device used with.

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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Submitter

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Contact Person: Santa Vucina
Title: Quality Management Representative
Email: Santa.Vucina@lightguide.com

Date of Submission: 09/30/2024

Device

Trade name: LGO-Surgical Laser Fibers
Common name: Laser Powered Surgical Instrument
Classification name: Laser Surgical Instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810, Product Code GEX)
Regulatory class: Class II

Predicate device

Trade name: Surgical Laser Fibers

510(k) number: K200234

Date of clearance: 02.25.2020

Common name: Laser Powered Surgical Instrument

Classification name: Laser Surgical Instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810, Product Code GEX)

This predicate has not been subject to a design-related recall.

Reference device

Trade name: FLARE™ single-use surgical laser fiber

510(k) number: K202702

Date of clearance: 02.26.2021

Common name: Laser Powered Surgical Instrument

Classification name: Laser Surgical Instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810, Product Code GEX)

Description of the device

LGO-Surgical Laser Fibers are a group of single use or reusable with up to 10 total uses EtO sterilized laser powered surgical instruments. They are intended for use in healthcare facilities or hospitals by physicians being familiar with the handling of medical laser devices, and with the therapeutic application of sterile medical optical fibers.
There are two primary product subgroups: Bare Fiber and Side Fire Fiber. Each subgroup encompasses various models on the market, which primarily vary in their distal end design, jacket materials, diameter, length, and usage (single use or 10x reusable). All variations of the LGO-Surgical Laser Fibers feature an SMA-905 connector or a custom special connector at the proximal end for compatibility with appropriate medical laser devices.

Indications for Use

LGO-Surgical Laser Fibers are intended to be used to deliver the laser radiation to the target tissue when used with any cleared/certified laser with operational wavelengths between 500 nm - 2200 nm equipped with SMA 905 standard or freestanding ferrule connector, as per the indications of the laser device used with.

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Comparison with predicate device

Specifications	Subject device	Predicate device	Reference device	Substantial Equivalence Discussion
Product name	LGO- Surgical Laser Fibers	Surgical Laser Fibers	FLARE™ single-use surgical laser fiber	-
510(k) number	K243147	K200234	K202702	-
Manufacturer	Light Guide Optics International Ltd.	Quanta System SPA	Realton (Suzhou) Medical Technology Co., Ltd.	-
Product code	GEX	GEX	GEX	Same
Indications for use	LGO-Surgical Laser Fibers are intended to be used to deliver the laser radiation to the target tissue when used with any cleared/certified laser with operational wavelengths between 500 nm - 2200 nm equipped with SMA 905 standard or freestanding ferrule connector, as per the indications of the laser device used with.	Surgical Laser Fibers are intended to be used to deliver the laser radiation to the target tissue with any cleared/certified surgical laser with operational wavelengths between 500nm – 2200nm equipped with SMA 905 or SMA 906 or compatible connector, as per the indications of the laser device used with.	FLARE™ single-use surgical laser fiber is intended to be used to deliver the laser radiation to the target tissue when used with compatible surgical lasers with operational wavelength between 532 nm- 2140 nm and equipped with SMA 905 compatible connector. FLARE™ single-use surgical laser fiber is indicated for use in general surgical applications for open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue and for lithotripsy.	*Similar, LGO-Surgical Laser Fibers do not have SMA 906 laser connector*
Core diameter	145 µm to 1000 µm	200 µm to 1000 µm	105, 200, 272, 365, 550, 600, 760, 940 µm	*LGO-Surgical Laser Fibers have a slightly smaller diameter than a predicate and a bit larger than reference*
Construction materials	Silica quartz glass, hard clad, silicone, polyimide, nylon, ETFE	Silica, fluoropolymer (hard clad), silicone, acrylate, teflon (ETFE), nylon, polyimide	Fused quartz	*LGO-Surgical Laser Fibers does not use acrylate as a construction material*
Operating wavelength	500 nm to 2200 nm	500nm – 2200nm	532nm ~ 2140nm	Same as predicate
Usage	Single use (SF and BF) Reusable with up to 10 total uses (RBF)	Single use Or reusable 10x	Single use	Same as predicate
Sterilization	Yes, Ethylene Oxide	Yes, Ethylene Oxide	Yes, Ethylene Oxide	Same
Proximal end	Connector with SMA 905 standard or freestanding ferrule	SMA 905 or SMA 906 or compatible connector	SMA-905 standard optical connector	*LGO-Surgical Laser Fibers have SMA 905 connector*

Non-clinical performance data

The following performance data were provided to support the evaluation:

- **Biocompatibility tests**

(ISO 10933-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process;
ISO 10933-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity;
ISO 10933-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization;
ISO 10933-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity;
ISO 10933-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials;
ISO 10933-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation)

- **Sterilization validation**

(ISO 11135:2014 Second edition Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices;
ISO 17665-1:2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices;
ISO 10933-5:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals [Including Amendment 1: Applicability of allowable limits for neonates and infants:2019])

- **Shelf-life validation**

(ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging;
ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes)

- **Sterility assurance level (SAL)**
- **Light transmission**
- **Functional tests before sterilization and after accelerated aging study:**
  - Product aseptic opening
  - Geometric parameters
  - Bend test
  - Beam profile
  - Transmission measurement
  - Connector pull test
  - Connector nut torque test
  - Quartz cap pull test
  - Other parts fixation
  - Visual inspection

All test results meet the pre-defined acceptance criteria and fulfill the intended use needs.

Clinical tests

No clinical testing was performed for this 510(k). Clinical data was not deemed to be necessary to establish equivalence between the subject device and predicative device.

Conclusion

The LGO-Surgical Laser Fibers exhibit comparable technological characteristics, including product code, indications for use, core diameter, material composition, operating wavelength range, and sterilization method, ensuring similar performance in surgical applications, when compared to the predicate device. Both devices are designed for single use or are reusable with up to 10 total uses, and utilize SMA 905 connectors for laser compatibility. While the LGO-Surgical Laser Fibers do not include SMA 906 compatibility and differ slightly in construction materials and core diameter, these differences do not raise new questions of safety or effectiveness.
In conclusion, the evidence presented in this summary supports the claim that the LGO-Surgical Laser Fibers are substantially equivalent to the predicate device.