April 29, 2022

Omni-Guide Holdings, Inc.
Carlos Acosta
Global Director Regulatory Affairs & Quality Assurance
46 Manning Road
Billerica, Massachusetts 01821

Re: K220189
Trade/Device Name: LISA Laser Surgical 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 12, 2022
Received: January 24, 2022

Dear Carlos Acosta:

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,

Purva Pandya, D.Eng.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220189

Device Name
Omni-Guide LISA Laser Surgical Fibers

Indications for Use *(Describe)*

Omni-Guide Holdings, Inc. single-use LISA Laser Surgical Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500nm – 2200nm have received regulatory clearance. Omni-Guide Holdings, Inc. single-use LISA Laser Surgical Fibers devices are intended for use with any cleared surgical laser with an SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adapters.

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.

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008_510(k)_Summary

Classification Name	Common Name	Trade Name/Proprietary Name
Part 878 General and Plastic Surgery 21 CFR §874.4680	**LISA Laser Surgical Fibers**	**Surgical Fibers**

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of Omni Guide knowledge.

Submitter:	Omni-Guide Holdings, Inc. 46 Manning Drive Billerica, MA 01821
Contact:	Carlos O. Acosta Phone: 617-551-4400 Ext. 563 Fax: 888-490-6020
510(k) Co-Author	Irina Fedorov Phone: 617-551-4400 Ext. Fax: 888-490-6020
Date of Preparation:	December 16, 2021
Type of 510(k) Submission:	Traditional
Device Identification:	**Trade Name:** LISA Laser Surgical Fibers **Classification Name:** Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class:	II
Product Code:	GEX
Panel Classification	General and Plastic Surgery (21 CFR §878.4810)

Predicate Device:	Primary Predicate Device: Laser Peripherals' Family of Surgical Fiber Optic Laser Delivery Device 510(k) = K170366
Device Description:	Omni-Guide Holding, Inc. LISA Laser Surgical Fibers are individually packed sterile devices to provide high quality surgical laser fiber optic delivery systems for laser surgery. The Fibers are for use in laser surgical procedures, including open, laparoscopic, or endoscopic ablation, coagulation, incision, and excision or vaporizing, in soft/hard-tissue application for which compatible surgical lasers are applicable. The key components are the fiber optic, and either an SMA-905, SMA-906, or manufacturer's specific connector. The fibers allow energy to be delivered to the surgical site through the use of glass fiber optic cable. Propagation of the light energy through the glass provides users the ability to direct the energy to the appropriate areas in the body. The Omni Guide Surgical Holding, Inc. single-use LISA Laser Surgical Fibers family of fibers are marketed to physicians as a sterile device within a typical Tyvek/poly pouch. Internally, the fiber is either secured in a wound circle with a Tyvek band, backer-card, or placed in a polyethylene tubing hoop to allow ease of removal. The construction of the fibers is dependent of the application to which it's marketed. There are two main methods of attaching the connector : crimp and adhesive. The crimp offers a reliable connection that will not be affected by heat whereas the epoxy allows a lower cost alternative where high temperatures are not an issue. All fibers offer various connector nuts, heat shrinks, abrasion jackets, strain reliefs or caps that best serve the environment where they are utilized.
Indications For Use:	Omni-Guide Holdings, Inc. single-use LISA Laser Surgical Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500nm – 2200nm have received regulatory clearance. Omni-Guide Holdings, Inc. single-use LISA Laser Surgical Fibers devices are intended for use with any cleared surgical laser with an SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adapters.

Substantial Equivalence Comparison Table

Comparison Table: Subject vs. Primary Predicate Devices

Characteristic	Subject Device LISA Laser Surgical Fiber	Primary Predicate, Laser Peripherals surgical fiber optic laser delivery devices K170366	Equivalence
510(k) Number	Pending	K170366	N/A
Product Code	GEX	GEX	Same/ Equivalent
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	**Same**
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	Same/equivalent
Components	Connector configurations offered suitable to multiple laser platforms	Connector configurations offered suitable to multiple laser platforms	Same/Equivalent
Technological characteristics	High OH or Low OH silica material w/low attenuation of light wavelengths between 532nm – 2100nm	High OH or Low OH silica material w/low attenuation of light wavelengths between 532nm – 2100nm	Same/Equivalent
Silica/Silica fibers/hard clad fibers	Fiber having a Numerical Aperture (NA) between 0.22 – 0.48	Fiber having a Numerical Aperture (NA) between 0.22 – 0.48	Same/Equivalent
Fiber distal tip	Multiple configurations of distal tips offered to provide the most suitable performance for the application	Multiple configurations of distal tips offered to provide the most suitable performance for the application	Same/Equivalent
Used with attachments	Core diameters are offered in a range of sizes suitable to user needs	Core diameters are offered in a range of sizes suitable to user needs	Same/Equivalent

	Connectors	SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adaptors	SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adaptors	Same/Equivalent
	Fiber Construction	Core – Fused Silica Clad – Fused Silica or Fluoropolymer Hard Cladding Buffer – Fluoropolymer Hard Cladding or Silicone Acrylate Jacket – Nylon, Polyimide, or Teflon	Core – Fused Silica Clad – Fused Silica or Fluoropolymer Hard Cladding Buffer – Fluoropolymer Hard Cladding or Silicone Acrylate Jacket – Nylon, Polyimide, or Teflon	Same/Equivalent
	Fiber Numerical Aperture	Fiber having a numerical Aperture (NA) between 0.22-048	Fiber having a Numerical Aperture (NA) between 0.22-048	Same/Equivalent
	Peak and Continuous Wave lengths	500nm-2200nm	500nm-2200nm	Same/Equivalent
	Power Ranges	1-300 Watts	1-300 Watts	Same/Equivalent
	Diameter	Core diameters are offered in a range of sizes suitable to user needs	Core diameters are offered in a range of sizes suitable to user needs	Same/Equivalent
	Fiber Distal Tip	Multiple configurations of distal tips offered to provide the most suitable performance for the application	Multiple configurations of distal tips offered to provide the most suitable performance for the application	Same/Equivalent
	Compatibility with surgical laser systems	Fibers are compatible with any cleared laser system with an appropriate connection system	Fibers are compatible with any cleared laser system with an appropriate connection system	Same/Equivalent

<table>
<tr><td></td><td>Sterilization</td><td>EtO</td><td>EtO</td><td>Same/Equivalent</td></tr>
<tr><td>Non-Clinical Performance Data:</td><td colspan="4">Bench testing on the subject device has shown the device to perform as intended with the same technological principle, fit, form, function and method of operating, as the single use fibers of K170366. Fibers included in this premarket notification were tested for conformance to the following performance standards:
<table>
<tr><td>Document Number</td><td>Title</td></tr>
<tr><td>ISO 11135-1</td><td>Sterilization of Health Care Products – Ethylene Oxide – Requirements for the development, validation and routine control sterilization process for medical devices</td></tr>
<tr><td>ISO 11607-1</td><td>Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems</td></tr>
<tr><td>ISO 10993-1</td><td>Biological Evaluation of Medical Devices – Part 1: Evaluation and testing</td></tr>
<tr><td>ISO 10993-5</td><td>Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity</td></tr>
<tr><td>ISO 10993-7</td><td>Biological Evaluation of Medical Devices – Part 7: Tests for Ethylene Oxide Sterilization Residuals</td></tr>
<tr><td>ISO 10993-10</td><td>Biological Evaluation of Medical Devices – Part 5: Tests for Irritation and Skin Sensitization</td></tr>
<tr><td>ISO 10993-11</td><td>Biological Evaluation of Medical Devices – Part 5: Tests for Systemic Toxicity</td></tr>
<tr><td>ISO 14971</td><td>Medical devices – Application of Risk Management to Medical Devices</td></tr>
<tr><td>ASTM D4169</td><td>Standard Practice for Performance Testing of Shipping Containers and Systems</td></tr>
<tr><td>ASTM F88-09</td><td>Standard Test Method for Seal Strength of Flexible Barrier Materials</td></tr>
<tr><td>ASTM F2096-11</td><td>Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)</td></tr>
<tr><td>ASTM F1980-07</td><td>Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices</td></tr>
<tr><td>ISO 14644-1</td><td>Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration</td></tr>
<tr><td>AAMI TIR12</td><td>Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities</td></tr>
<tr><td>ISO 17664</td><td>Sterilization of medical devices—Information to be provided by the manufacturer for the processing of sterilizable medical devices</td></tr>
<tr><td>ISTA Project 2A</td><td>Series, Partial-Simulation Performance Test</td></tr>
<tr><td>ASTM F56-13</td><td>Standard Practice for Assessment of Hemolytic Properties of Materials, 2013</td></tr>
<tr><td>ASTM F619-14</td><td>Standard Practice for Extraction of Medical Plastics</td></tr>
</table>
The performance test reports focus on the key features of the fiber. These included the following testing (depending on need):
Power & Energy input versus output
Homogeneity of output light (spot check, beam profile)
High-power testing
Bend radius testing
Pull testing
Feature specific testing (i.e. Nav Tip tested for ability to traverse deflected endoscope)
Much of the testing performed was based on a specific (usually new) feature approach. Those features indicated in the attachments are 1) Scatter Free Fiber, 2) Expanded transmission of laser wavelength/energy, and 3) LaseGuide Nav distal tip configuration. These test reports show the features identified are proven to be safe and effective. Other reports are similar in that they indicate passed testing of specific features or overall products</td></tr>
<tr><td>Animal Testing</td><td colspan="4">Animal testing is not needed to support the safety and efficacy of the single use fibers that are subject of this premarket notification.</td></tr>
<tr><td>Clinical Performance</td><td colspan="4">Clinical testing is not needed to support the safety and efficacy of the single use fibers that are subject of this premarket notification.</td></tr>
</table>

Conclusion:	The single-use optical fibers that are the subject of this premarket notification use identical or similar technology as that of the single-use fibers of the K170366 510(k). Testing of key performance characteristics demonstrates that the single-use optical fibers that are the subject of this premarket notification can be used safely and effectively for the proposed indications for use. The Omni Guide single-use Surgical Holding, Inc. LISA Laser Surgical Fibers are considered to be substantially equivalent to the single-use fibers of the predicate K170366.