April 21, 2023

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

Re: K230819
Trade/Device Name: OmniGuide RFID 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: March 17, 2023
Received: March 24, 2023

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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K230819

Device Name
OmniGuide PRIMA Surgical Laser fibers

Indications for Use *(Describe)*

Omni-Guide Holdings, Inc. single-use OmniGuide PRIMA Surgical Laser 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 OmniGuide PRIMA Surgical Laser 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.

008_510(k)_Summary

Classification Name	Common Name	Trade Name/Proprietary Name
Part 878 General and Plastic Surgery 21 CFR §874.4680	Laser Instrument, Surgical	OmniGuide Prima Surgical Laser 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.

Omni-Guide Holdings, Inc. is submitting this 510(k) of equivalent OmniGuide Prima Surgical Laser Fibers equivalent to our predicate devices, LISA Laser Surgical Fibers and cleared under Omni-Guide Holdings, Inc. own 510(k) K220189. LightGuide Optics International Ltd., is our Contract Manufacturer (CMO), a CMO of equivalent fibers (reference FDA Establishment Registration & Device Listing ID# 3012669557: - Powered Laser Surgical Instrument - Slimline Endo Fibers; Slimline Endo SIS Fibers; Slimline EZ Fibers; Slimline EZ SIS Fiber; Slimline Fibers; Slimline GI Fiber; Slimline GI SIS Fiber; Slimline SIS Fibers). The manufacturing process of OmniGuide Prima Surgical Laser Fibers and sterilization are the same process to current FDA fibers manufactured by LGO, as well as the predicate device LISA Laser Surgical Fibers.

OmniGuide Prima Family of Surgical Laser Fibers and the Primary Predicate Device, share the same intended use, indication for use, human factors, design, performance, materials. manufacturing, packaging, mechanical safety, biocompatibility, sterilization. There minor difference in the technological characteristics do not raise any questions of safety or performance. Performance data demonstrates the OmniGuide are as safe and effective as the listed predicate. OmniGuide Prima Surgical Laser Fibers are substantially equivalent to its predicate device.

Submitter:	Omni-Guide Holdings, Inc. 43 Manning Drive Billerica, MA 01821
Contact:	Carlos O. Acosta Phone: 617-551-4400 Ext. 563 Fax: 888-490-6020
Date of Preparation:	February 22, 2023
Type of 510(k) Submission:	Special
Device Identification:	**Device Name and Classification 807.92(a)(2):** **Trade Name:** OmniGuide Prima Surgical Laser 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: OmniGuide LISA Laser Family of Surgical Laser Fibers Delivery Device 510(k) = K220189

Device Description:	Omni-Guide Holding, Inc. OmniGuide Prima Surgical Laser Fibers are individually packed sterile devices indicated to provide high quality surgical laser fiber optic delivery systems for laser surgery. The Fibers are intended for use in laser surgical procedures including, but not limited to open, laparoscopic, or endoscopic ablation, coagulation, incision, and excision or vaporizing in any soft/hard-tissue application for which compatible lasers are applicable. Product description, length, laser wavelength compatibility can be found in Section 15 of this 510(k) Premarket Notification. The key components of this system are the SMA-905, SMA-906 with RFID and Manufacturer's specific RFID connectors and the Fiber Optic, these fibers may be used in a variety of laser-based surgical cases. Per [807.92(a)(4)].
Intended Use: Indications For Use:	Omni-Guide Holdings, Inc. single-use OmniGuide PRIMA Surgical Laser 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 OmniGuide PRIMA Surgical Laser 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** OmniGuide Prima Surgical Laser Fibers	**Primary Predicate, OmniGuide LISA Laser Surgical Fibers, K220189**	**Equivalence**
510(k) Number	Pending	K220189	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

	Intended Use **Indication for Use**	Omni-Guide Holdings, Inc. single-use OmniGuide PRIMA Surgical Laser 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 OmniGuide PRIMA Surgical Laser 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.	OmniGuide LISA Laser Surgical Fibers are intended for use with any cleared surgical laser with an SMA 905 connector, SMA 906 connectors, or manufacturer specific connectors and adaptors OmniGuide 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.	Same/Equivalent 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) between0.22-048	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
	Sterilization	EtO	EtO	Same/Equivalent

<table>
<tr><td>Non-Clinical Performance Data:</td><td>Bench testing (see Section 21) on the subject device has shown the device to perform as intended with the same technological principle, fit, form, function, method of operating, including but not limited to the listed date below. The subject device is substantially equivalent to the predicate device and reference devices in the following attributes:

➢ Indications for Use
➢ Intended Use
➢ Sterilization Technique
➢ Performance Characteristics
➢ Energy used and delivered
➢ Design
➢ Materials
➢ Packaging
➢ Shelf-Life
➢ Safety
➢ Manufacturing
➢ Clinical setting
➢ Mechanism Action
➢ Anatomical Site
➢ Biocompatibility</td></tr>
<tr><td>Performance Testing Summary</td><td>The performance test reports focus on the key features of the fiber. These included the following testing (depending on need):
1. Power & Energy input versus output
2. Homogeneity of output light (spot check, beam profile)
3. High-power testing
4. Bend radius testing
5. Pull testing
6. Feature specific testing was conducted to demonstrate equivalence to the predicate device and reference devices: safety, performance, integrity, stability, transport, label integrity, packaging of sterilized fibers. Reference section 21 for the following tests: Performance test of Prima 150 laser fiber on RevoLix HTL; Performance test of Prima 1000 laser fiber on RevoLix HTL; Performance test of PrimaSidefire laser fiber on RevoLix HTL; Test of mechanical stability of Prima 150 micron laser fiber, Test of mechanical stability of Prima 1000 micron laser fiber, and Test of mechanical stability of Prima 550 micron laser fiber,
Additional Feature testing conducted in the predicate Device LISA Laser Surgical Fiber K220189. Much of the testing performed was based on a specific feature approach. Those features indicated in K220189 performance testing were 1) Scatter Free Fiber, 2) Expanded transmission of laser wavelength/energy, and 3) distal tip configuration, 4 Nav Tip tested for ability to traverse deflected endoscope. 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>This product category does not require animal testing.</td></tr>
<tr><td>Clinical Performance Data:</td><td>This product category does not require clinical testing.</td></tr>
<tr><td>Compliance to Standards</td><td>
<table>
<tr><th>Document Number</th><th>Title</th></tr>
<tr><td>ISO 11135-1</td><td>Sterilization of Health Care Products – Ethylene Oxide – Requirements for the development, validation and routine control of a 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>
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	ISO 14971	Medical devices -- Application of Risk Management to Medical Devices
	ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems
	ASTM F88-09	Standard Test Method for Seal Strength of Flexible Barrier Materials
	ASTM F2096-11	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
	ASTM F1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
	ISO 14644-1	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
	AAMI TR12	Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities
	ISO 17664	Sterilization of medical devices—Information to be provided by the manufacturer for the processing of sterilizable medical devices
	ISTA Project 2A	Series, Partial-Simulation Performance Test
	ASTM F56-13	Standard Practice for Assessment of Hemolytic Properties of Materials, 2013
	ASTM F619-14	Standard Practice for Extraction of Medical Plastics
Device Description	The Family of OmniGuide Prima Surgical Laser Fibers are individually packed sterile devices indicated to provide high quality surgical laser fiber optic delivery systems for laser surgery. The Fibers are intended for use in laser surgical procedures including open, laparoscopic or endoscopic ablation, coagulation, incision, and excision or vaporizing in any soft/hard-tissue application for which compatible lasers are applicable. Product description, length, laser wavelength compatibility can be found in Section 14 of this 510(k) Premarket Notification. The history of laser fibers originated with the development of lasers used in the medical community. They have been prevalent in surgical applications for the past 63 years. 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 technology of inputting light energy into a fiber optic cable in order to provide a workable tool for physicians has been relatively unchanged since the inception of medical lasers.	
All Omni Guide Surgical Holding, Inc. OmniGuide Prima Surgical Laser 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 coil circle with a Tyvek band, backer-card, or placed in a polyethylene tubing hoop to allow ease of removal. Often sold in quantities of 1-5 for single use, they are packaged in a shelf box and distributed in a separate shipper. The reusable fibers are marketed in single unit shelf boxes. 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.		
Conclusion:	A direct comparison of key characteristics demonstrates that Omni Guide Surgical Holding, Inc. OmniGuide Prima Surgical Laser Fibers are substantially equivalent/same as the predicate device in terms of materials of construction, energy use and delivery, chemical/electrical/mechanical/thermal safety, manufacturing, intended uses, surgical use of the devices, technological considerations, packaging, safety and performance characteristics [807.92(a)(4)]. Omni Guide Surgical Holding, Inc. OmniGuide Prima Surgical Laser Fibers family of laser fibers as safe, as effective and perform as well as the predicate devices. The small difference to the predicate device does not raise different questions of safety and efficacy, rather guarantees trained clinicians the use of validated FDA cleared laser fibers.	

	Performance testing was conducted in order to demonstrate the specifications and performance of OmniGuide Prima Surgical Laser Fibers and to verify that no different questions of safety and effectiveness have been raised due to the small modification's introduction. Test and assessment results indicated that the subject OmniGuide Prima Surgical Laser Fibers perform in accordance with its requirements and specifications, in similarity to its predicate family and do not raise new safety or efficacy risks/questions.