April 2, 2021

LEONI Fiber Optics, Inc.
℅ Patsy Trisler
Regulatory Consultant
Qserve Group US, Inc.
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K201171
Trade/Device Name: LEONI 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 2, 2021
Received: March 4, 2021

Dear Patsy Trisler:

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 U. Pandya -S

Purva Pandya
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201171

Device Name

LEONI™ Laser Fibers

Indications for Use *(Describe)*

LEONI™ Laser Fibers (BareFiber Disposable, BareFiber Reusable and Endoprobe Disposable) are intended for use with any cleared surgical laser with an SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adaptors and are indicated for use in laser-based surgical applications and procedures that are performed with compatible lasers operating at wavelengths between 500nm and 2200nm, which have been cleared.

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."

510(k) Summary – K201171

I. SUBMITTER

Submitter Name:	LEONI Fiber Optics, Inc.
Submitter Address:	209 Bulifants Blvd. Williamsburg, VA 23188
Contact Person:	Donnie Cobb, Regulatory Affairs and Quality Manager
Contact Phone:	757-258-4805
Date Prepared:	30 March 2021

II. DEVICE

Trade Name:	LEONI™ Laser Fibers
Common Name	Fiber Optic Delivery System
Regulatory Name	Powered Laser Surgical Instrument
Classification	21 CFR 878.4810
Class	2
Product Codes	GEX

III. PREDICATE DEVICE

Primary Predicate Device:	K170366, Laser Peripherals Family of Bare Laser Fibers, Laser Peripherals, LLC
Reference Device:	K050738, FT Fiber Optic Delivery Systems, FiberTech GmbH

IV. INTENDED USE AND INDICATIONS FOR USE

LEONI™ Laser Fibers (BareFiber Disposable, BareFiber Reusable and Endoprobe Disposable) are intended for use with any cleared surgical laser with an SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adaptors and are indicated for use in laser-based surgical applications and procedures that are performed with compatible lasers operating at wavelengths between 500nm and 2200nm, which have been cleared.

V. DEVICE DESCRIPTION

Device Identification and Technological Characteristics

The fiber optic delivery systems are accessories designed to deliver optical energy to soft or fibrous tissue in general surgical applications, in combination with any SMA-compatible laser system also indicated for the same applications.

They are composed of silicon, polyimide, acrylate, and polyamide.

The device systems are available in multiple sizes and with multiple tip shapes and handpiece configurations.

The fiber optics are available in reusable, and single use disposable devices that are prepackaged sterile. The reusable fiber optic systems may be reused only after the optical fiber tip is cleaned according to the Instructions for Use.

VI. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE			
	NEW DEVICE	**PRIMARY PREDICATE**	**REFERENCE**
510(k) NUMBER	K201171	K170366	K050738
DEVICE NAME	LEONI™ Laser Fibers	Laser Peripherals Family of Bare Laser Fibers	FT Fiber Optic Delivery Systems
MANUFACTURER	LEONI Fiber Optics, Inc.	Laser Peripherals, LLC	FiberTech GmbH
PRODUCT CODE	GEX	GEX	GEX
REGULATORY NAME	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument
COMMON NAME	Fiber Optic Delivery System	Fiber Optic Delivery System	Fiber Optic Delivery System
CLASSIFICATION	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
INTENDED USE/ INDICATIONS FOR USE	LEONI™ Laser Fibers (BareFiber Disposable, BareFiber Reusable and Endoprobe Disposable) are intended for use with any cleared surgical laser with an SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adaptors and are indicated for use in laser-based surgical applications and procedures that are performed with lasers operating at wavelengths between 500nm and 2200nm, which have been cleared.	Laser Peripherals surgical fiber optic laser delivery devices are intended for use with any cleared surgical laser with an SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adaptors The Laser Peripherals Laser Fiber is indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500nm – 2200nm have received regulatory clearance.	The disposable contact and the reusable non-contact Fiber Optic Delivery System is intended to vaporize, coagulate and incise and excise tissue and are cleared for any indication for which compatible Nd: YAG, Ho YAG, KTP and Diode Laser Systems have been cleared by the FDA. The Laser peripherals bare laser fibers, ENT fibers and Endoprobes are intended for use in laser surgical procedures for cutting, coagulating, or vaporizing in any soft tissue application for which compatible Nd: YAG, Ho: YAG, KTP and Diode lasers have been cleared
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	SMA 905 and adapters
Fiber Construction	Core – Fused Silica Clad – Fused Silica or Fluoropolymer Hard Cladding Buffer – Fluoropolymer Hard Cladding or Silicone Acrylate	Core - Fused Silica Clad – Fused Silica or Fluoropolymer Hard Cladding Buffer – Fluoropolymer Hard Cladding or Silicone Acrylate	Core - Fused Silica Clad – Fused Silica or Fluoropolymer Hard Cladding Buffer – Fluoropolymer Hard Cladding or Silicone Acrylate

	Jacket - Nylon, Polyimide, or Teflon	Jacket - Nylon, Polyimide, or Teflon	Jacket - Nylon, Polyimide, or Teflon
Fiber Numerical Aperture	0.22 – 0.48	0.22 – 0.48	0.22 – 0.37
Fiber Wavelength Range	500nm – 2200nm	500nm – 2200nm	532 – 2127nm
Fiber Core 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	200 - 1000µm
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	Multiple configurations of distal tips offered to provide the most suitable performance for the application
Sterilization	Sterile, via Ethylene Oxide	Sterile, via Ethylene Oxide	Sterile, via Ethylene Oxide
Single Use or Reusable	Both for BareFiber Single Use for Endoprobe	Both	Both
Biocompatible	Biocompatible, according to ISO 10993 testing	Biocompatible, according to ISO 10993 testing	Biocompatible, according to ISO 10993 testing
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	Fibers are compatible with any cleared laser system with an appropriate connection system

VII PERFORMANCE AND SAFETY TESTING	
Animal Testing:	This product category does not require animal testing.
Clinical Testing:	This product category does not require human clinical testing.
Laboratory Testing:	The following technological characteristics of the fibers were evaluated and data reports submitted in the 510(k): • Laser power testing in relaxed and strained/bent configurations using a cleared surgical laser generator. • Pull testing of the connector bond • Optical performance (transmission) • Mechanical performance, including tensile and bending testing
Sterilization Validation	Testing according to ISO 14973 has been performed to validate the ethylene oxide sterilization method assures a SAL of 10^{-6}. Further testing was conducted to validate the reprocessing methods for cleaning and sterilization of the devices labeled for reuse.

Shelf Life	The shelf life has been established, via real time and accelerated testing, to be 5 years.
Biocompatibility Testing:	Testing, according to ISO 10993 confirms the LEONI™ Laser Fiber is biocompatible and non-toxic and safe for its intended use.

VIII COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intended use, composition, specifications, and modes of operation are substantially equivalent to the Primary Predicate Device.

The differences are noted in the Substantial Equivalence Comparison Table (above). Those differences, when compared to the Primary Predicate, do not raise new questions related to safety and effectiveness.

VIX CONCLUSION

Based on the comparisons provided and the data submitted in this 510(k), it can be concluded the LEONI™ Laser Fibers are substantially equivalent to the Predicate devices.