July 30, 2021

W & R Investments, LLC dba Laser Engineering
Robert Rudko
Chief Scientist
113 Cedar Street, SuiteS5
Milford, Massachusetts 10757

Re: K211761
Trade/Device Name: UltraLase Flexible CO2 Laser Waveguide
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: July 6, 2021
Received: July 7, 2021

Dear Robert Rudko:

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
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)*

K211761

Device Name
UltraLase Flexible CO2 Laser Waveguide

Indications for Use *(Describe)*

The UltraLase Flexible CO_2 Laser Waveguide is indicated for use with CO_2 laser systems for general and plastic surgery procedures, neurosurgery, and ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, gynecology and urology procedures. It is used to deliver laser energy for incision, excision, ablation, vaporization, and coagulation of soft tissues.

The UltraLase Flexible CO_2 Laser Waveguide can be used in open surgical procedures and endoscopic procedures.

The indications for use for which the delivery system is used are dependent upon the cleared indications for use of the laser system and laser system accessories to which it is attached

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.

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SPECIAL 510(K) SUMMARY (K211761)

Applicant:

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Tel: (508) 520-2552

Contact Person:
Robert I. Rudko, Ph.D.
Chief Scientist
r.rudko@laserengineering.com

Date Prepared: May 19, 2021

Device Name: UltraLase CO_2 Laser Waveguide

Proprietary Name:	UltraLase Flexible CO_2 Laser Waveguide Model # HWG505 and HWG305
Classification Name:	Laser Surgical Instrument
Classification:	878.4810
Product Code:	GEX

Predicate Devices:

The UltraLase Flexible CO_2 Laser Waveguides (K211761) Model HWG505 and HWG305 are modifications of the currently marketed devices (K112166) Model HWG500-2.0-3.0 and the HWG300-2.0-3.0 respectively.

Reference device:

In addition, the UltraLase Flexible CO_2 Laser Waveguide is substantially equivalent to the FiberLase CO_2 Laser Waveguide (K100384) manufactured by Lumenis, Ltd.

Device Description:

The UltraLase Flexible CO_2 Laser Waveguides are laser delivery systems for use in surgical procedures where a flexible delivery system would allow easier and more efficient delivery of laser energy to the targeted tissue.

The waveguide consists of a flexible silica capillary who's inside wall has been coated with a durable coating that is highly reflective at the intended wavelength of use. A fiber optic connector is attached to the proximal end of the

waveguide and the waveguide is covered with a protective sleeve.

The UltraLase Flexible CO_2 Laser Waveguide is designed to operate at 10.6µm and has a broad enough transmission band to accommodate any laser operating in this region.

The laser energy is coupled into the waveguide using the correct focusing lens and travels down the waveguide by multiple bounces off the inner reflective surface, exiting to the tissue at the distal end.

The laser waveguides have either a 905 SMA connector or a 953 ST connector attached and can therefore be used with any CO_2 Laser that is compatible with one of these connectors. The waveguides are 2 meters long.

It is recommended that a purge gas be used to flow a gas through the waveguide to keep the inner channel of the waveguide free of debris.

The waveguides delivery systems are supplied sterile for single use.

Indications for Use:

The UltraLase Flexible CO_2 Laser Waveguide is indicated for use with CO_2 laser systems for general and plastic surgery procedures, neurosurgery, ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, gynecology and urology procedures. It is used to deliver laser energy for incision, excision, ablation, vaporization, and coagulation of soft tissues.

The UltraLase Flexible CO_2 Laser Waveguide can be used in open surgical procedures and endoscopic procedures.

The indications for use for which the delivery system is used are dependent upon the cleared indications for use of the laser system and laser system accessories to which it is attached.

Technological Characteristics Compared to Cleared Device:

The new device has the same performance characteristics, the same labeling and the same indications for use as the currently cleared device. The *only* difference between the devices is that the protective sleeve on the cleared device is a fluoropolymer heat-shrinkable tubing and the protective sleeve on the new product is Tefzel 207, a modified ETFE (ethylene-tetrafluoroethylene) fluoroplastic that is applied when the waveguide is being drawn.

Both materials are ETO sterilizable and are biocompatible.

The reason this change is being made is that it is easier and less expensive to apply the protective sleeve during the drawing process than to

manually put on heat shrink tubing later in the waveguide assembly process.

Substantial Equivalence:

Comparison chart between the cleared Laser Engineering UltraLase CO_2 Laser Fiber (K112166) and the submission UltraLase CO_2 Laser Fiber (K211761):

Product Name	UltraLase CO_2 Laser Waveguide	Ultralase CO_2 Laser Waveguide
510(k) Number	K112166	K211761
Manufacturer	Laser Engineering	Laser Engineering
Part Numbers	HWG300-2.0-3.0 HWG500-2.0-3.0	HWG305 HWG505
Indications for use	The UltraLase Flexible CO_2 Laser Waveguide is indicated for use with CO_2 laser systems for general and plastic surgery procedures, neurosurgery, and ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, gynecology and urology procedures. It is used to deliver laser energy for incision, excision, ablation, vaporization, and coagulation of soft tissues. The UltraLase Flexible CO_2 Laser Waveguide can be used in open surgical procedures and endoscopic procedures. The indications for use for which the delivery system is used are dependent upon the cleared indications for use of the laser system and laser system accessories to which it is attached.	The UltraLase Flexible CO_2 Laser Waveguide is indicated for use with CO_2 laser systems for general and plastic surgery procedures, neurosurgery, and ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, gynecology and urology procedures. It is used to deliver laser energy for incision, excision, ablation, vaporization, and coagulation of soft tissues. The UltraLase Flexible CO_2 Laser Waveguide can be used in open surgical procedures and endoscopic procedures. The indications for use for which the delivery system is used are dependent upon the cleared indications for use of the laser system and laser system accessories to which it is attached.
Principle of Operation	Hollow Light-Conducting Waveguide	Hollow Light-Conducting Waveguide
Operating Wavelength	10.6microns	10.6microns
Maximum input power	30 Watts	30 Watts

Power Transmission	Greater than 70% for 500µ waveguide, Greater than 40% for 300µ fiber	Greater than 70% for 500µ waveguide, Greater than 40% for 300µ fiber
Inner Diameter	500µ for HWG500-2.0-3.0, 350µ for HWG300-2.0-3.0	500µ for HWG505 350µ for HWG305
Fiber Length	200 cm	200 cm
Fiber Outer Diameter	1.2 – 1.3 mm	0.750 - 1.08 mm
Materials Used	Fused Silica Capillary Acrylate Clad fluoropolymer heat-shrinkable tubing	Fused Silica Capillary Acrylate Clad Tefzel 207 Buffer
Material Manufacturer	Leoni Fiber Optics	Leoni Fiber Optics
Internal Reflective Coating	Silver/Silver Iodide	Silver/Silver Iodide
Connector	905 SMA or 953 ST	905 SMA or 953 ST
Packaging	Sealed Tyvek Bag	Sealed Tyvek Bag
Sterilization Method	ETO	ETO
Shelf Life	3 Years	1 Year

Summary of Nonclinical Tests:

A number of non-clinical tests were performed on the new device as shown in the chart below. The acceptance criteria were the same as the acceptance criteria for the predicate device.

Test Performed	Acceptance Criteria (K211761)	Acceptance Criteria (K112166)
Epoxy strength Test	15 Newtons for 15 seconds	15 Newtons for 15 seconds
Intracutaneous Study	No evidence of irritation	No evidence of irritation
Muscle Implant Study	Microscopic reaction not significant	Microscopic reaction not significant
Systemic Toxicity Study	No mortality or systemic toxicity	No mortality or systemic toxicity
Sterilization Validation	Sterility assurance level of 10^{-6}	Sterility assurance level of 10^{-6}
ETO Residual	Meets requirements of ISO 10993-7	Meets requirements of ISO 10993-7
Bioburden	Less than 100	Less than 100
Shelf-Life	1 Year	3 Years

Package Integrity	Visual Inspection, Bubble Leak Test, Seal Strength Test	Visual Inspection, Bubble Leak Test, Seal Strength Test
Performance Testing	Meets 70% transmission criteria after sterilization.	Meets 70% transmission criteria after sterilization

The only difference between the new device and the predicate is the shelf life which is 3 years for the predicate and 1 year for the new device. This was done for business reasons since these devices have always been used within 1 year of manufacture. Aside from that, the submission device (K211761) and the predicate device (K112166) perform the same.

Summary of Clinical Tests:

No clinical tests were performed.

Conclusion:

The summary includes the conclusions drawn from the nonclinical tests (discussed above) that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device. 807.92(b)(3)