June 3, 2021

Gyrus ACMI, Inc.
Julie Acker
Program Manager, Regulatory Affairs
800 West Park Drive
Westborough, Massachusetts 01581

Re: K211401
Trade/Device Name: SOLTIVE Laser System (SOLTIVE Pro SuperPulsed Laser, SOLTIVE Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories)
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: May 5, 2021
Received: May 6, 2021

Dear Julie Acker:

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)*
K211401

Device Name
SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories)

Indications for Use *(Describe)*

The SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories) is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

Urology:
• Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]• Laser Resection of the Prostrate (LRP)• Laser Enucleation of the Prostate (LEP)• Laser Ablation of the Prostate (LAP)• Transurethral Incision of the Prostate (TUIP) • Condylomas• Urethral strictures• Lesions of external genitalia• Bladder neck incisions (BNI)• Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors• Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi• Treatment of distal impacted fragments remaining in the ureters following lithotripsy

Lithotripsy and Percutaneous Urinary Lithotripsy Indications:
• Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones • Endoscopic fragmentation of calculi • Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed

Gastroenterology:
Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:
• Appendectomy • Angiodysplasia • Polyps • Colorectal cancer • Biopsy • Telangiectasias
• Gall Bladder calculi • Telangiectasias of the Osler-Weber-Renu disease • Biliary/Bile duct calculi • Vascular Malformation • Ulcers • Gastritis • Gastric ulcers • Esophagitis • Duodenal ulcers • Esophageal ulcers • Non Bleeding Ulcers • Varices • Pancreatitis • Colitis • Haemorrhoids • Mallory-Weiss tear • Cholecystectomy • Gastric Erosions
• Benign and Malignant Neoplasm

Gynecology:
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

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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SOLTIVE™ LASER SYSTEM

510(k) PREMARKET NOTIFICATION

K211401

SECTION 5.0 – 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc. *SOLTIVE™ LASER SYSTEM*
(SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories)

General Information

Contract Manufacturer:	IPG Medical Corporation 377 Simarano Drive Marlborough, MA 01752, USA
510(k) Submitter:	Gyrus ACMI, Inc. 800 West Park Drive Westborough, MA 01581
Establishment Registration Number:	3003790304
Contact Person:	Julie Acker Program Manager Regulatory Affairs Phone: 484-294-6981 Email: julie.acker@olympus.com
Date Prepared:	May 5, 2021

Device Description

Trade Name:	SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories)
Generic/Common Name:	Laser Instrument for Use in General Surgery
Classification Name:	Laser Instrument for Use in General Surgery
Regulation/CFR Citation Number:	21 CFR 878.4810
Product Code:	GEX
Classification:	Class II
Review Panel:	Gastroenterology/Urology

Predicate Devices

SOLTIVE Laser Systems	K183647

Comparison to Predicate Device:

The subject of this 510(k) is a modification to the SOLTIVE Laser Systems to update the application software to Version 2.1. The device hardware design is identical to the predicate. The subject change to the software updates the graphical user interface and corresponding changes to the Instructions for Use. The predicate Soltive application software offers standard factory presets for procedures commonly performed using the Soltive Laser System. The modified software Version 2.1 adds a factory preset within the Lithotripsy menu for Ureteral Stone procedures, as well as other enhancements.

Product Description

The SOLTIVE Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories) is a thulium laser, producing a pulsed beam of coherent near-infrared light (1940 nm) upon activation by a footswitch. The beam is then directed to the treatment zone by means of an optical fiber coupled to a handpiece. An integrated LED touch screen gives the user control over the necessary laser system parameters. The SOLTIVE Laser System is equipped with a 550 nm aiming beam.

The SOLTIVE Laser System is produced in two models, the SOLTIVE™ Premium SuperPulsed Laser and SOLTIVE™ Pro SuperPulsed Laser. The Premium has a maximum power output of 60 Watts and a maximum Frequency output of 2400 Hz. A secondary, foldable screen is provided. The Pro can operate at a maximum power of 35 Watts and Frequency limited to 100Hz. Both systems are operated with a wireless footswitch or wired footswitch, and both systems can utilize an auxiliary video monitor to display operating parameters. The Premium and Pro Laser must be used with a SOLTIVE Laser Fiber, offered in diameters from 150 – 940 microns.

The system includes:

- Laser console
- Laser fibers – sterile single use and reusable
- Foot pedal, wireless or wired
- Accessories – power cord, HDMI cable, safety goggles/glasses, fiber cutter,
- fiber cleaver, fiber gripper, sterilization tray, cart

The devices do not incorporate medicinal substances, tissues, or blood products. The laser fibers are single-use and reusable, and both single-use and reusable are initially sterilized by Ethylene Oxide. Fibers are compatible with the Olympus endoscope models as listed on the IFU.

Technological Characteristics

The proposed SOLTIVE Laser System with application software Version 2.1 has the identical intended use, design, and scientific technology as the predicate SOLTIVE Laser System (K183647). The subject modification is solely an update to the application software to add a Ureteral Stone preset to the menu of factory presets, and other enhancements. There are no new issues of safety or effectiveness with the proposed device.

Material

No material changes were made to the SOLTIVE Laser System cleared under K183647.

Indications for Uses

The indications for use of the modified device, as described in its labeling, have not changed as a result of the modification.

The SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories) is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

Urology
• Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]
• Laser Resection of the Prostrate (LRP)
• Laser Enucleation of the Prostate (LEP)
• Laser Ablation of the Prostate (LAP)
• Transurethral Incision of the Prostate (TUIP)
• Condylomas
• Urethral strictures
• Lesions of external genitalia
• Bladder neck incisions (BNI)
• Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
• Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi
• Treatment of distal impacted fragments remaining in the ureters following lithotripsy

Lithotripsy and Percutaneous Urinary Lithotripsy Indications
• Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones
• Endoscopic fragmentation of calculi

• Treatment of distal impacted fragments of steinstrasse when guide wire cannot be Passed

Gastroenterology
Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitis
- Haemorrhoids
- Cholecystectomy
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions
- Benign and Malignant Neoplasm

Gynecology
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

Compliance to Voluntary Standards

The design of the SOLTIVE Laser System complies with the following standards:

Standard	Title
EN ISO 14971:2019	Medical devices -- Application of risk management to medical devices
ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
IEC 60601-1:2005+A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60825-1:2014	Safety of laser products - Part 1: Equipment classification and requirements
IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 60601-2-	Medical electrical equipment - Part 2-22: Particular

Standard	Title
22:2007+A1:2012	requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60601-1-6:2010+A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62304:2006+A1:2015	Medical device software - Software life cycle processes
ISO 11607-1:2019	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11135:2014	Sterilization of health care products -- Ethylene oxide: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing
ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
ISO 10993-7:2008+COR1:2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
ASTM F 1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1886/F1886M:2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F88-15/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ISO 17665-1:2006/R2013	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 14937:2009/R2013	Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISTA Procedure 3A 2018	Packaged Products for Parcel Delivery System Shipment 70kg (150 lb) or less
ASTM D4169-16	Performance Testing of Shipping Containers and Systems
ASTM F2096-11	Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak)

Summary of Sterilization and Shelf-Life Discussion

SOLTIVE SuperPulsed Laser Fibers Single-use and SOLTIVE SuperPulsed Laser Fibers Reusable are provided sterile. The devices are sterilized by Ethylene Oxide to a provide sterility assurance level of $10^{-}6$.

The Shelf-Life period for the Single-use fibers was determined via testing and through an analysis of the shelf-life stability of the materials used in the design of the device, as well as an analysis of the packaging materials and processes used with other Gyrus ACMI devices. Shelf-life studies are on file to support the labeled shelf life.

Summary of All Performance Testing (bench, clinical, non-clinical)

Software verification tests were conducted in support of the subject software modification. Testing demonstrated that all performance requirements met the prescribed acceptance criteria.

Substantial Equivalence

Substantial equivalence is demonstrated by acknowledged verification/validation activities. The subject devices have identical technology, performance, dimensions, and materials. The differences to the predicate device SOLTIVE Laser Systems are:

- Revised software to update the graphical user interface to add a Ureteral Stone preset to the menu of Lithotripsy presets and other enhancements.
- Updated Instructions for Use to align with updated graphical user interface.

Equivalence Comparison Table:

Gyrus ACMI SOLTIVE Laser System			
Design Feature	**Proposed (Software Version 2.1)**	**Predicate K183647 (Software Version 2.0)**	**Comparison**
Intended Use	The SOLTIVE Laser System is intended for use in surgical procedures such as open laparoscopic and endoscopic, involving endoscopic ablation, vaporization, excision, incision, resection, coagulation and hemostasis of soft tissue in medical specialties including: Urology, lithotripsy, gastroenterology, arthroscopy, discectomy, gynecology, ENT and general surgery.	The SOLTIVE Laser System is intended for use in surgical procedures such as open laparoscopic and endoscopic, involving endoscopic ablation, vaporization, excision, incision, resection, coagulation and hemostasis of soft tissue in medical specialties including: Urology, lithotripsy, gastroenterology, arthroscopy, discectomy, gynecology, ENT and general surgery.	Identical
Function of Device	Thulium Laser generator with fiber optic delivery	Thulium Laser generator with fiber optic delivery	Identical
Mechanics of Action	Light/energy absorption by target tissues	Light/energy absorption by target tissues	Identical
Laser Source	Thulium	Thulium	Identical
Accessories	Surgical fibers (reusable and single use) available in following nominal core diameters (150, 200, 365, 550, 940 µm)	Surgical fibers (reusable and single use) available in following nominal core diameters (150, 200, 365, 550, 940 µm)	Identical
Biocompatible	Yes	Yes	Identical
Sterilization (Single-use fibers)	Ethylene Oxide 10-6	Ethylene Oxide 10-6	Identical
Single Use & Reusable Fibers	Yes	Yes	Identical

Conclusion:

In summary, the Gyrus ACMI SOLTIVE Laser System is substantially equivalent to the predicate device and presents no new questions of safety or effectiveness.