



January 27, 2023

Gyrus ACMI, Inc.  
Jon Gilbert  
Regulatory Affairs Consultant to Gyrus ACMI, Inc.  
800 West Park Drive  
Westborough, MA 01581

Re: K221306  
Trade/Device Name: SOLTIVE Laser System  
Regulation Number: 21 CFR§ 878.4810  
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in  
Dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: December 16, 2022  
Received: December 19, 2022

Dear Jon Gilbert:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Mark J. Antonino -S**

Mark J. Antonino, M.S.

Assistant Director

DHT3B: Division of Reproductive,  
Gynecology and Urology Devices

OHT3: Office of GastroRenal, ObGyn,

General Hospital and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K221306

**Device Name**

SOLTIVE Laser System

**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 Prostate (LRP) • Laser Enucleation of the Prostate (LEP) • Laser Ablation of the Prostate (LAP) • Transurethral Incision of the Prostate (TUIP) • Condylomas • Urethral/ureteral 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 renal calculi • Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

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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Department of Health and Human Services  
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[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

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## 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
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

## Gynecology

Open, endoscopic (including hysteroscopic) 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)

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**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 3003790304

Number: Contact Person: Jon Gilbert fbo Julie Acker  
Regulatory Affairs Consultant  
Phone: 906.361.3237  
Email: jgilb.raca@gmail.com

Date Prepared: May 3, 2022

**Device Description**

Trade Name: SOLTIVE Laser System

Generic/Common Name: Laser Instrument for Use in  
General Surgery

Classification Name: Laser Surgical Instrument for Use  
in General and Plastic Surgery and  
in Dermatology

Regulation/CFR Citation Number: 21 CFR 878.4810

Product Code: GEX

Classification: Class II

Review Panel: Gastroenterology/Urology

**Predicate Devices**

SOLTIVE Laser Systems K211401, K183647

### **Comparison to Predicate Device:**

The subject of this 510(k) is a labeling modification to the SOLTIVE Laser Systems. The device hardware and software design is identical to the predicate. The subject change to the labeling clarifies currently cleared Instructions for Use.

### **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 stripper and 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 modified labeling has the same intended use, design, and scientific technology as the predicate SOLTIVE Laser System (K183647). The subject modification is solely an update to clarify the use of the laser system in urological and gynecological tissues.

### **Material**

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

### **Indications for Uses**

The indications for use of the modified device, as described in its labeling, have not changed the intended clinical applications 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 / ureteral 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
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- Biopsy
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- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitis
- Haemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

### **Gynecology**

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

### **Compliance to Voluntary Standards**

<b>Standard</b>	<b>Title</b>
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



<b>Standard</b>	<b>Title</b>
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 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)**

Performance testing was conducted in support of the predicate devices and equivalently applies to the subject device as the labeling clarifications fall within the existing performance envelope of the laser system. Testing demonstrated that all performance requirements met the prescribed acceptance criteria, including the proposed labeling change.

### **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:

- Clarified labeling for urological and gynecological surgery.
- Updated Instructions for Use to align with updated labeling.

**Equivalence Comparison Table:**

<b>Gyrus ACMI SOLTIVE Laser System</b>			
<b>Design Feature</b>	<b>Proposed</b>	<b>Predicate K211401</b>	<b>Comparison</b>
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.	Equivalent
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.