August 23, 2024

Olympus Surgical Technologies America
Apurva Joshi
Regulatory Affairs Specialist II
800 W Park Drive
Westborough, Massachusetts 01581

Re: K242191
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: July 25, 2024
Received: July 25, 2024

Dear Apurva Joshi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sharon M. Andrews -S

for Mark Antonino
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K242191

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/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.

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 Gynecology • 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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)

I. Submitter

Contract Manufacturer:	IPG Medical Corporation 377 Simarano Drive Marlborough, MA 01752, USA
510(k) Submitter:	Gyrus ACMI, Inc. 9600 Louisiana Ave. North Brooklyn Park, MN 55445 USA
Establishment Registration Number:	3011050570
Contact Person:	Apurva Joshi Regulatory Affairs Specialist II Phone: 1-617-512-5935 Email: apurva.joshi@olympus.com
Alternate Contact:	Julie Acker Program Manager, Regulatory Affairs Phone: 1-(484)294-6981 Email: julie.acker@olympus.com
Date Prepared:	August 22, 2024

II. Device

Trade Name:	SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories)
Generic/Common Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name:	Powered Laser Surgical Instrument
Regulation/CFR Citation Number:	21 CFR 878.4810
Product Code:	GEX
Classification:	Class II
Review Panel:	General Surgery Devices

III. Predicate Device

SOLTIVE Laser Systems	K221306

This predicate has been subject to design-related recalls.

IV. Device Description:

The SOLTIVE™ Laser System is a thulium fiber 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 comprised of a choice of two models - Premium Laser System and Pro Laser System, laser fibers and accessories. The Premium laser has a maximum power output of 60 Watts and a maximum Frequency output of 2400 Hz and a secondary, foldable screen is provided. The Pro laser can operate at a maximum power of 35 Watts and Frequency output limited to 100Hz. Both systems are compact, designed to fit onto an optional laser cart and are operated with a footswitch (wired or wireless). The Soltive Laser System must be operated with a Soltive Laser Fiber, offered in quartz core diameters from 150 – 940 microns.

The system includes:

- Laser console
- Sterile laser fibers – single-use and reusable options in sizes 150um, 200um, 365um, 550um, and 940um
- Footswitch, wireless or wired options.
- Accessories – power cord, HDMI cable, safety goggles/glasses, fiber strippers, fiber cleaver, blast shields, cart

The devices do not incorporate medicinal substances, tissues, or blood products. The Soltive laser fibers are provided in single-use and reusable options, and both single-use and reusable fibers are initially sterilized by Ethylene Oxide.

V. Indications For Use

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

VI. Comparison of technological characteristics with the predicate device

Gyrus ACMI SOLTIVE Laser System			
Design Feature	**K242191**	**K221306 Predicate**	**Comparison**
Indications for Use comparison	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.	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.	Same
Function of Device	Thulium Fiber Laser generator with fiber optic delivery	Thulium Fiber Laser generator with fiber optic delivery	Same
Mechanics of Action	Light/energy absorption by target tissues	Light/energy absorption by target tissues	Same
Laser Source	Thulium	Thulium	Same
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)	Same
Major Software version	2.2	2.2	Same
Configuration file version	V5.1	V5.0	Different
IFU Soltive Laser System	PN0015551 Revision AJ	PN0015551 Revision AH	Different

<table>
<tr><th colspan="5">Gyrus ACMI SOLTIVE Laser System</th></tr>
<tr><th>Design Feature</th><th colspan="2">K242191</th><th>K221306
Predicate</th><th>Comparison</th></tr>
<tr><td>Preset Treatment Parameter</td><td colspan="2">Average Power 2 W- 18 W</td><td>Average Power 8 W- 56 W</td><td>Different</td></tr>
<tr><td rowspan="4">Lithotripsy 1

Lithotripsy 2

Lithotripsy 3

Manual Mode</td><td>Left Pedal</td><td>Right Pedal</td><td rowspan="4">For different Lithotripsy options frequency and energy have average power in the range of 8W-56W</td><td rowspan="4">Different</td></tr>
<tr><td>Decreased Average Power (Decreased Frequency)</td><td>Decreased Average Power (Decreased Frequency, Increased Energy)</td></tr>
<tr><td>Decreased Average Power (Decreased Frequency, Increased Energy)</td><td>Decreased Average Power (Decreased Frequency, Increased Energy)</td></tr>
<tr><td>Decreased Average Power (Decreased Frequency, Decreased Energy)</td><td>No Change</td></tr>
<tr><td colspan="2">Decreased Average Power (Decreased Frequency, Increased Energy)</td></tr>
</table>

The subject device has similar technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device. The difference between subject and predicate is the values of energy and/or frequency programmed in the software configuration file representing Preset Treatment Parameters. These technological differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

VII. Performance Data

1. Non-Clinical Tissue testing

Soft Tissue Thermal Effect Testing was performed to demonstrate that the laser system delivers clinically acceptable tissue thermal effect depths and widths due to accidental tissue exposure during lithotripsy. Each revised Preset Treatment Parameter was tested in comparison to the corresponding current Preset Treatment Parameter using porcine ureter tissue and 150µm and 940µm core diameter fibers. Laser setting values tested consist of a combination of minimum average power values, maximum average power values, and the preset treatment parameter values. All data sets demonstrated statistical equivalency with p-value greater than 0.05 between the data set containing the predicate preset and the data set containing revised presets, meeting the acceptance criteria of the Design Verification testing. This demonstrates the tissue effect from accidental exposure over the range of laser settings has remained unchanged despite the changes to the preset energy parameters.

Simulated Stone Ablation Testing was performed using 150um and 940um core diameter fibers and simulated stones to characterize stone ablation rate of revised preset energy parameters.

2. Software Verification and Validation

Software verification and validation regression testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software documentation for this device was considered as a "enhanced", since a failure or flaw of any device software function(s) could present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.

VIII. Conclusion:

Based on the non-clinical tissue testing and software validation and verification testing, the modified device was found to be substantially equivalent to the predicate device.