July 24, 2026

Olympus Surgical Technologies America
Dolan Mills
Sr. Program Manager, Regulatory Affairs
800 West Park Drive
Westborough, MA 01581

Re: K261221
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: II
Product Code: GEX
Dated: June 19, 2026
Received: June 22, 2026

Dear Dolan Mills:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261221

Please provide the device trade name(s).

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

Please provide your Indications for Use below.

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.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

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

510(k) Submitter:	Gyrus ACMI, Inc. 9600 Louisiana Ave. North Brooklyn Park, MN 55445 USA
Establishment Registration Number:	3011050570
Contract Manufacturer:	IPG Medical Corporation 225 Cedar Hill Street Marlborough, MA 01752, USA
Contact Person:	Dolan Mills Sr. Program Manager, Regulatory Affairs Phone: 1-901-355-0007 Email: dolan.mills@olympus.com
Date Prepared:	June 19, 2026

II. Device

Trade Name:	SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories)
Regulation 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	K242191

This predicate has been subject to design-related recalls which are related to this submission.

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 (PLS) and Pro Laser System (SLS), 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, footswitch (wired and wireless), 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 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 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	**Subject**	**K242191 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

Gyrus ACMI SOLTIVE Laser System			
Design Feature	**Subject**	**K242191 Predicate**	**Comparison**
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	2.3	2.2	Similar
Configuration file version	V6.0	V5.0	Similar
Patient Contacting Materials (Fibers)	Quartz Silicone Tefzel	Quartz Silicone Tefzel	Same
IFU, Soltive Laser System and Fibers	PN0015551, revision AK PN0015555, revision AE PN0014679, revision AG	PN0015551, revision AJ PN0015555, revision AC PN0014679, revision AF	Similar

The subject device has identical 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 a minor change to the Fiber strain relief material and protective cap material at the proximal end of the device, which is not patient contacting, and an increase of the Fiber shelf-life from 1 to 3 years. These differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

VII. Performance Data

Non-clinical bench testing was performed to verify that the changed material and shelf-life meets all applicable product requirements. The results support the claim of substantial equivalence of the subject device to the predicate device.

Mechanical and Functional: Verification and comparison bench tests were conducted to evaluate the mechanical and functional performance as compared to the predicate. Tests included dust cover function, flammability testing, and strain relief pull testing.

Result - All testing passed, meeting the acceptance criteria of the Design Verification testing. This demonstrates the fibers are equivalent to the predicate.

Compliance to Standards

The following standards have been used during the design and testing of the subject device system in total.

Applied standards:

- ISO 14971:2019
- ISO 15223-1:2021+AMD1:2025
- IEC 60601-1:2005+AMD1:2012+AMD2:2020
- IEC 60601-1-2:2020
- IEC 60825-1:2014
- IEC 62366-1:2015+AMD1:2020
- IEC 60601-2-22:2019
- IEC 60601-6: 2010+A1, A2:2020
- IEC 62304:2006 + A1 2015
- ANSI/AAMI ISO 11135: 2014+A1:2018
- ISO 11607-1:2019
- ASTM F1980-16:2021
- ASTM F1886/F1886M-09:2016
- ASTM F88/F88M-21
- ASTM D4169:2022
- ASTM F2096:2019
- ISO 17665:2024
- ISO 17664-1:2021
- ISO 10993-1:2018
- ISO 10993-5:2009
- ISO 10993-7:2019
- ISO 10993-10:2021
- ISO 10993-11:2017
- ISO 10993-17:2013
- ISO 10993-18:2022
- ISO 10993-23:2025
- ISO 14937:2009

VIII. Conclusion:

Based on the bench testing, the modified device was found to be substantially equivalent to the predicate device.