September 19, 2025

IPG Medical Corporation
Kevin O'Conell
Director of Regulatory Affairs
225 Cedar Hill Street
Marlborough, MA 01752

Re: K251100
Trade/Device Name: IPGTFL-02
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: August 10, 2025
Received: August 20, 2025

Dear Kevin O'Conell:

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.

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

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

510(k) Number *(if known)*
K251100

Device Name
IPGTFL-02

Indications for Use *(Describe)*
The IPGTFL-02 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 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 with integrated detection of calculi and mucosal tissue by StoneSense module that reduces exposure of mucosal tissue to laser energy and reduces resulting damage to mucosal tissue
• Treatment of distal impacted fragments remaining in the ureters following lithotripsy

Lithotripsy and Percutaneous Urinary Lithotripsy:
• Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate dihydrate 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 hemostasis) 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
• Hemorrhoids
• 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K251100

510(k) Summary

Prepared on: 2025-08-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	IPG Medical Corporation
Applicant Address	225 Cedar Hill Street Marlborough MA 01752 United States
Applicant Contact Telephone	774-633-5903
Applicant Contact	Mr. Kevin O'Conell
Applicant Contact Email	koconnell@ipgmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	IPGTFL-02
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Class II
Regulation Number	21 CFR 878.4810
Product Code(s)	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232568	IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers, and Accessories	GEX

Device Description Summary

21 CFR 807.92(a)(4)

IPGTFL-02 is a desktop, portable thulium laser source and controller used with specific surgical fibers (single-use & reusable) 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 laser system generates non-ionizing radiation which is transferred to the relevant anatomical treatment site through surgical fibers that serve as the delivery vehicle from the laser energy generator to the treatment site.

The laser system includes a universal, three-pedal footswitch that can operate in wired and wireless mode for hands-free control. The system can utilize a customer-supplied, medical grade external surgical monitor to display endoscope video as well as the device's user interface.

The laser system's front panel includes a surgical fiber connection port and a touchscreen with a user interface. The rear panel includes electrical and interface cable ports. The laser system may be placed on an optional, mobile cart. The system can utilize an auxiliary video monitor to display operating parameters.

The laser system can operate at a maximum power output of 60 watts in CW, regular and advanced Pulsed modes with a maximum frequency output of 2400 Hz and a maximum pulse energy of 6 Joules.

The laser system must be operated with the IPG Medical Surgical Fibers. The surgical fibers are flexible optical fibers that deliver the laser energy to the target tissue. The surgical fibers are the only patient-contacting components of the IPGTFL-02.

The purpose of this 510(k) is to add an optional module called StoneSense™ for lithotripsy procedures. During these procedures it is possible that the fiber tip loses contact or quasi-contact with the stone which is undesirable. The module is designed to detect if the object in contact or quasi-contact with the distal fiber tip is "Stone" or "Not Stone". If Stone is not detected, the system will not allow emission of the laser. The addition of Stone sense will add an indication for the device.

Also, three advanced power modes have been added:
• Fragmentation Pulse - Special pulse shape, optimized for stone ablation into large fragments.
• Minimal Carbonization Pulse - Special pulse shape for soft tissues vaporization, incision and excision with minimization of tissue carbonization.
• Enucleation Pulse - Special pulse shape, developed for enucleation procedure to maximize thermo-mechanical separation of adenomic tissue and capsule with simultaneous strong hemostasis effect.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The IPGTFL-02 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.

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• Ablation and resection of bladder tumors, urethral tumors, and ureteral tumors
• Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi with integrated detection of calculi and mucosal tissue by StoneSense module that reduces exposure of mucosal tissue to laser energy and reduces resulting damage to mucosal tissue
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• Appendectomy
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• Biliary/Bile duct calculi
• Vascular Malformation
• Ulcers
• Gastritis
• Gastric ulcers
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• Duodenal ulcers
• Esophageal ulcers
• Non Bleeding Ulcers
• Varices
• Pancreatitis
• Colitis
• Hemorrhoids

• Mallory-Weiss tear
• Cholecystectomy
• Gastric Erosions
• Benign and Malignant Neoplasm

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use statement has been amended to include the StoneSense module. After the indication of of "Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi" the following was added:
"with integrated detection of calculi and mucosal tissue by StonseSense module that reduces exposure of mucosal tissue to laser energy and reduces resulting damage to mucosal tissue."
This addition falls within the same intended use as the predicate which is: incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue.

Technological Comparison

21 CFR 807.92(a)(6)

The IPGTFL-02 is similar to the predicate in fundamental technological characteristics. Both devices are Thulium Fiber lasers, with a wavelength of 1920 nm - 1960 nm, peak power of 125, 250 and 500 W, average power of 2-60 W and use optical fiber cable with the identical size and patient contacting materials. There are some technology characteristics that are different. They are described below:

The operating modes are similar. Instead of Assistant Mode in predicate, IPGTFL-02 uses Guided Mode. The predicate used the location of the stone, stone size and stone density to determine the recommended treatment parameters. IPGTFL-02 uses location of the stone, flow rate and stone density to determine recommended treatment parameters. It was found that using flow rate instead of stone size allowed better match between relevant clinical situation and optimal laser settings.

The surgical fibers are similar to the surgical fibers in the predicate submission. The patient contacting area of the fiber optics cables are identical in both devices. The method of sterilization and SAL of the sterilization cycle remained the same. The shelf life has been extended to 3 years.

Both devices have Standard Power Modes, Regular Pulse and Continuous Wave (CW), and Minimal Retropulsion Pulse (MRP) for predicate. IPGTFL-02 has three additional Advanced Power Modes which are: Fragmentation Pulse, Minimal Carbonization Pulse and Enucleation Pulse.

Similar to MRP, these three power modes modify the pulse to improve the effect on tissue or stone without compromising safety profile.

StoneSense: The StoneSense module is a new feature for lithotripsy procedures. Due to retropulsion (movement of stone during lithotripsy), inadvertent movement of the scope or the patient, or error in positioning of the fiber tip by the operator, it is possible that the fiber tip is no longer in contact or is in quasi-contact with the stone, with laser pulses no longer being incident on the stone but possibly a) on mucosal tissue or b) within the fluid away from the stone, both of which are undesirable. Laser pulses incident on mucosal tissue can cause ablative or coagulative burn injuries, which may lead to unwanted side effects. Laser pulses within the ambient fluid cause heating of the fluid, increasing load on the irrigation system and decrease stone ablation efficiency. IPG Medical has developed StoneSense technology to detect if the object in contact or quasi-contact with the distal fiber tip is "Stone" or "Not Stone". If Stone is not detected, the system will not allow emission of the laser.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

IEC 60601-1:2005/AC 1:2006/A1:2012/AC1:2014/AMD2:2020
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014; IEC 60601-1-2:2014/A1:2020
Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6: Edition 3.2 2020-07 Usability
IEC 62366-1: 2015+AMD1:2020 Part 1: Application of usability engineering to medical devices
IEC 62304: 2006/AMD1: 2015 Medical device software (SW)
IEC 60601-2-22: 2019 Particular requirements for basic safety and essential performance of surgical, cosmetic etc.
IEC 60825-1: 2014 Safety of laser products – Part 1: Equipment classification and requirements

Ex-vivo testing was completed to compare effects such as fragmentation efficiency, ablation depth, coagulation width and carbonization grade and coagulation of the new power modes to the predicate device.
Testing of the StoneSense Module was performed by comparing StoneSense determination of "Stone or "Not Stone" during a simulated procedure with a known value of "Stone or "Not Stone".

Not applicable