March 13, 2024

IPG Medical Corporation
Alexander Wybornov
Vice Predisent
225 Cedar Hill Street
Marlborough, Massachusetts 01752

Re: K232568
Trade/Device Name: IPG Medical Family of Thulium Fiber Lasers, Surgical 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: February 20, 2024
Received: February 20, 2024

Dear Samuel Wade:

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,

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

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)*
K232568

Device Name
IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers, and Accessories

Indications for Use *(Describe)*
The IPG Medical Family of Thulium Fiber Lasers, Surgical 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 indication: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

Urology: ● Ablation ofBenign 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 ● 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 dihydrate 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 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.

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510(k) Summary

Manufacturer Identification:

IPG Medical Corporation
225 Cedar Hill Street
Marlborough, MA 01752
Phone: 508-506-2800
Establishment Registration #3020221089
Contact Person: Alexander Vybornov (508-506-2718)

Date Prepared:

August 18, 2023

Device Identification:

- Device Trade Name: IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers, and Accessories
- Device Common Name: Laser Instrument for Use in General Surgery
- Classification Name: Laser Instrument, Surgical, Powered
- Classification Number: 21 CFR 878.4810
- Product Code: GEX
- Device Class: Class II
- Review Panel: Gastroenterology / Urology

Identification of Predicate Devices:

Trade Name	Manufacturer	510(k)
SOLTIVE Laser System (primary predicate)	Gyrus, ACMI, Inc.	K211401

Device Description:

The IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories are portable thulium fiber lasers 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 IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories 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 IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories includes wireless (optional) and wired, three-pedal footswitches for hands-free control. The system can utilize an auxiliary video monitor to display operating parameters.

The IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories front panel includes a surgical fiber connection port and a touchscreen with a user interface. The back panel includes electrical and interface cable ports. The Laser Console may be placed on an optional mobile cart.

The IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories includes:

- Laser Console
- Footswitches, wired or wireless (optional)
- Surgical Fibers
- Accessories:
    - Power cord
    - Video output cable
    - Video adapter
    - Safety glasses
    - Fiber stripper
    - Fiber cleaver
    - Blast shield
    - Interlock connector
    - Mobile cart (optional)

The IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories operates on emission wavelengths between 1920 and 1960 nm.

The IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories can operate at a maximum power output of 60 watts and a maximum frequency output of 2400 Hz with a maximum pulse energy of 6 Joules.

The IPG Medical Family of Thulium Fiber Lasers must be operated with the IPG Family of Surgical Fibers. The surgical fibers are flexible optical fibers that deliver the laser energy to the target tissue. The IPG Family of Surgical Fibers are offered in a range of core diameters from 150 microns – 940 microns and include single use,

reusable and ball tip options. The surgical fibers are the only patient-contacting components of the IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories.

Indications for Use:

The IPG Medical Family of Thulium Fiber Lasers, Surgical 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 ureteraltumors
- 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 dihydrate 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 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.

Comparison to Predicate Devices:

The IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories is compared to the primary predicate, SOLTIVE Laser System, and the additional predicate, the vela XL Laser System, in the table below.

Feature	IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories	SOLTIVE™ Laser System (#K211401) Primary Predicate
Intended Use	The IPG Medical Family of Thulium Fiber Lasers, Surgical 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	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

	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 • Treatment of Distal Impacted Fragments remaining in the Ureters following Lithotripsy <u>Lithotripsy and Percutaneous Urinary Lithotripsy Indications:</u> • Endoscopic Fragmentation of Urethral, Ureteral, Bladder, and Renal Calculi including Cystine, Calcium Oxalate, Monohydrate and Calcium Oxalate Dihydrate Stones • Endoscopic Fragmentation of Calculi	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. <u>Lithotripsy and Percutaneous Urinary Lithotripsy Indications:</u> • 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 <u>Gastroenterology</u>: Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including: • Appendectomy • Angiodysplasia • Polyps • Colorectal cancer • Biopsy

Feature	IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories	SOLTIVE™ Laser System (#K211401) Primary Predicate
	• 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:	• 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.

Feature	IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories	SOLTIVE™ Laser System (#K211401) Primary Predicate
	Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue.	

Feature	IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories	SOLTIVE™ Laser System (#K211401) Primary Predicate
Laser Type	Thulium	Thulium
Laser Class	Class 4	Class 4
Laser Emission Mode	Pulsed and CW	Pulsed
Average Power	2 – 60 W adjustable	2 – 60 W adjustable
Peak Optical Power	125 W to 500 W	125 W to 500 W
Repetition Rate	Up to 2400 Hz	Up to 2400 Hz
Operating Temp Range	15 – 30 deg C	15 – 30 deg C
Cooling	Air cooled	Air cooled
Beam Delivery	Flexible Optical Fiber	Flexible Optical Fiber
Control Panel	10" LCD Color Touchscreen	7'' and 12.1" LCD Color Touchscreen Displays
Electrical	100-240V ≈ 1200VA 50/60 Hz	100-240V ≈ 1200VA 50/60 Hz
Weight	≤40 kg	≤40 kg
Dimensions	43 x 29 x 62 cm	30 x 37 x 56 cm

Feature	IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories	SOLTIVE™ Laser System (#K211401) Primary Predicate
(HxWxD)		
Fiber Sizes	150, 200, 365, 550, 940 µm	150, 200, 365, 550, 940 µm
Fiber Sterilization	EtO	EtO

The intended use and indications for use are identical between the IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories and the primary predicate, the SOLTIVE Laser System. The technological characteristics of the IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories and the SOLTIVE Laser System are either identical or very similar; with one key difference.

The IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories is different from the primary predicate, the SOLTIVE Laser System, in that it can be used in continuous wave (CW) mode whereas the SOLTIVE Laser System cannot. Therefore, an additional reference predicate, the vela XL Laser System, was identified. The vela XL Laser System is a thulium fiber laser that is used in CW mode. While the vela XL Laser System has a broader set of indications for use, all the IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories indications for use are included within the vela XL Laser System indications for use.

The IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories is considered substantially equivalent to the primary predicate SOLTIVE Laser System in Pulsed mode and is considered substantially equivalent to the additional reference predicate, the vela XL Laser System, for use in CW mode.

Non-Clinical and Performance Testing

The IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories was tested according to the following standards:

Non-Clinical and Performance Testing	Standards Used
Electrical Safety and EMC	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)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 disturbances - Requirements and tests
	IEC 60601-2-22:2012, Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
	IEC 60825-1:2014 (in accordance with Laser Notice 56), Safety of laser products - Part 1: Equipment classification and requirements

Biocompatibility	ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
	ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
	ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
	ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Test for systemic toxicity
	ISO 10993-12:2012, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
	ISO 10993-12:2021, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
Packaging and Sterile Barrier	ISO 11607-1:2019, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems
	ISO 11607-2:2019, Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
	ISO 14644-1:2015. Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
	ISO 14644-2:2015. Cleanrooms and associated controlled environments.
	ISO 14698-1:2003. Cleanrooms and associated controlled environments – Bio-contamination control -- Part 1: General principles and methods.
	ISO 14698-2:2003. Cleanrooms and associated controlled environments – Bio-contamination control - Part 2: Evaluation and interpretation of bio-contamination data.
	ISO 15223-1:2016. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
	F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
	F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
	F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials
	F2096-11 (2019), Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
	ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems
	ASTM D4332-14, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
	ISTA 3A. Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb.) or Less.
	ISTA 3B. Packaged-Products for Less-Than-Truckload (LTL) Shipment.
Sterilization (Surgical Fibers)	ISO 11135:2014, Medical devices – Validation and routine control of ethylene oxide sterilization
	ISO 10993-7:2008/AMD 1:2019, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
	ISO 11138-1:2017. Sterilization of health care products - Biological indicators - Part 1: General Requirements.
	ISO 11737-1:2018. Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
	ISO 11737-2:2019. Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

	ISO 17665:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
Human Factors	IEC 62366-1:2015, Medical devices – Part 1: Application of usability engineering to medical devices
	IEC 60601-1-6:2013, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
Risk Management	ISO 14971: 2019. Medical devices - Application of risk management to medical devices.
	ISO 22442-1:2020 Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management
Software	IEC 62304:2006/A1:2016, Medical device software – Software Life Cycle Processes
Measuring Systems	BS EN ISO 10012:2003. Measurement management systems. Requirements for measurement processes and measuring equipment.

Performance Testing included:

- Design Verification Testing: Laser system
- Design Verification Testing: Surgical fibers
- Shelf-Life testing for the Surgical Fibers
- Side-by-Side Comparison Testing

All testing demonstrated that the IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories met its design requirements.

Comparative testing (bench and animal tissue testing and analysis) between the IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories and the primary predicate and additional predicate devices showed equivalent device performance and tissue response.

Conclusions

Testing supports a substantial equivalence determination of the IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories in comparison to the primary predicate device, the SOLTIVE Laser System, and the additional predicate device, vela XL Laser System. Technological differences between the IPG Medical Family of Thulium Fiber Lasers, Surgical Fibers and Accessories and the predicate devices do not raise any different or new types of safety or effectiveness questions.