November 24, 2025

Guangzhou Potent Medical Equipment Joint-Stock Co., Ltd.
Zhengzhou Li
Room 208, Building C, No. 3, Juquan Road
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K252787
Trade/Device Name: Thulium Fiber Laser System (TFL-A); Thulium Fiber Laser System (TFL-B)
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 20, 2025
Received: September 2, 2025

Dear Zhengzhou Li:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.11.24 15:15:24 -05'00'

for Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252787

Device Name
Thulium Fiber Laser System (TFL-A); Thulium Fiber Laser System (TFL-B)

Indications for Use *(Describe)*
The Thulium Fiber Laser System is intended for incision, excision, resection, ablation, coagulation, hemostasis and vaporization of soft tissue, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

Urology
• Ablation of Benign Prostatic Hyperplasia (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
• 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
• Angiodysplasia
• Polyps
• Colorectal cancer
• Biopsy
• Telangiectasias
• Gall Bladder calculi
• Telangiectasias ofthe 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

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
#K252787

Submitter / Contact Information

Field	Information
Submitter Name	Guangzhou Potent Medical Equipment Joint-Stock Co., Ltd.
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Email	potent_medical_public@potent-medical.com
Date Prepared	July 15, 2025

Device Information

Field	Information
Device Trade Name	Thulium Fiber Laser System
Models	TFL -A/ TFL -B
Common Name	Thulium Fiber Laser System
Regulation Name	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation Number	21 CFR 878.4810
Regulatory Class	Class II
Product Code	GEX
Panel	General and Plastic Surgery

Predicate and Reference Devices

Type	Device	Manufacturer	510(k) Number
Predicate	Fiber Dust	Quanta System SpA	K210142

Device Description

The Thulium Fiber Laser System is a pulsed solid-state Thulium fiber laser system that delivers energy at a wavelength of 1940 nm through optical fibers for soft tissue surgery and stone fragmentation. The system utilizes a diode-pumped Thulium-doped fiber laser medium, and the laser energy is transmitted to the target site via standard optical fibers. The system is designed for surgical applications requiring precise tissue ablation, coagulation, and stone fragmentation.

The system includes an intuitive touchscreen interface, dual-pedal foot switch,, integrated cooling system, and comprehensive safety features including emergency stop, door interlock, key switch, and real-time monitoring of laser parameters.

Indications for Use

The Thulium Fiber Laser System is intended for incision, excision, resection, ablation, coagulation, hemostasis and vaporization of soft tissue, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

Urology

- Ablation of Benign Prostatic Hyperplasia (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

- 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

·Angiodysplasia

·Polyps

·Colorectal cancer

·Biopsy

·Telangiectasias

·Gall Bladder calculi

·Telangiectasias ofthe 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 MalignantNeoplasm

Gynecology

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

Technological Characteristics

Comparison to Predicate Device

Feature	**Subject Device**	**Predicate Device (K210142)**	**Comparison**
Laser Source	Thulium fiber laser	Thulium laser	Same technology
Wavelength	1940 nm	1940 nm	Same
Emission	CW/Pulsed	CW/Pulsed	Same
Pulse Duration	0.04ms～15ms	0.1 to 15 ms	Similar range
Pulse Energy	Up to 6 Joule	0.02 to 6 J	Similar range
Frequency	Up to 2500 Hz	1 to 2500 Hz	Similar
Max Average Power	TFL -A (60W) TFL -B (40W)	60 W	Similar
Aiming Beam	520nm laser < 3 mW	532 nm laser <5 mW	Equivalent
Cooling System	Air cooling	Air cooling system	Equivalent
User Interface	Touchscreen display	Digital interface	Equivalent
Safety Features	Emergency stop, interlock, key switch	Standard safety features	Equivalent

Performance Testing

Standards Conformance

The subject device was tested according to the following recognized consensus standards:

- **IEC 60601-1:2020 (Edition 3.2)**
  Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-2:2020 (Edition 4.1)**
  Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- **IEC 60601-2-22:2019 (Edition 4.0)**
  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 (Edition 3.0)**
  Safety of laser products -- Part 1: Equipment classification and requirements

Software Verification and Validation

Software development and validation were performed in accordance with:

- **IEC 62304:2006 + A1:2015**
  Medical device software -- Software life cycle processes
- **FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**

Non-Clinical Performance Testing

Comprehensive performance testing was conducted including:

- Stone Breakage testing
- Tissue perforation testing
- Output power accuracy testing
- Pulse energy and duration verification
- Wavelength stability testing
- Safety interlock functionality testing

All testing demonstrated that the device performs as intended and meets all specified requirements.

Substantial Equivalence Conclusion

The Thulium Fiber Laser System has the same intended use and similar technological characteristics as the predicate device (K210142). Both devices:

- Utilize thulium laser technology at 1940 nm wavelength
- Provide similar output parameters and operating modes

- Are intended for the same surgical applications
- Incorporate equivalent safety features

Minor differences in user interface design, maximum power output ranges, or control features do not raise new questions of safety or effectiveness. The comprehensive non-clinical performance testing supports that the subject device is as safe, as effective, and performs as well as the predicate device.

Based on the comparison of intended use, technological characteristics, and performance data, the Thulium Fiber Laser System is **substantially equivalent** to the identified predicate device.