November 20, 2025

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

Re: K253007
Trade/Device Name: PT-OF-X-S Series Laser Fiber
(Models: PT-OF-A-S, PT-OF-B-S, PT-OF-C-S, PT-OF-D-S, PT-OF-E-S, PT-OF-F-S)
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: September 15, 2025
Received: September 19, 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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.11.20 15:40:50 -05'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253007

Device Name
PT-OF-X-S Series Laser Fiber (Models PT-OF-A-S, PT-OF-B-S, PT-OF-C-S, PT-OF-D-S, PT-OF-E-S, PT-OF-F-S)

Indications for Use *(Describe)*
PT-OF-X-S Series Laser Fiber (Models PT-OF-A-S, PT-OF-B-S, PT-OF-C-S,PT-OF-D-S, PT-OF-E-S, PT-OF-F-S) is indicated for to deliver laser energy from a source to the target tissue in laser surgery applications, when used with any cleared/certified laser with wavelengths 1940nm - 2100nm equipped with SMA 905 standard connector.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY
K253007

Submitter Information

Field	Information
Submitter Name	Guangzhou Potent Medical Equipment Joint-Stock Co., Ltd.
Address	Room 208, Building C, No. 3, Juquan Road, Huangpu District, Guangzhou, Guangdong Province,510000, China
Phone	+86 -20 3739 6970
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Contact Person	Zhengzhou Li
Email	potent_medical_public@potent-medical.com
Date Prepared	August 15, 2025

Device Information

Field	Information
Device Trade Name	PT-OF-X-S Series Laser Fiber (Models: PT-OF-A-S, PT-OF-B-S, PT-OF-C-S, PT-OF-D-S, PT-OF-E-S, PT-OF-F-S)
Models	PT-OF-A-S, PT-OF-B-S, PT-OF-C-S, PT-OF-D-S, PT-OF-E-S, PT-OF-F-S
Common Name	Laser Powered Surgical Instrument
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 Device

Type	Device	Manufacturer	510(k) Number
Primary Predicate	LGO-Surgical Laser Fibers	Light Guide Optics International Ltd.	K243147

Device Description

The PT-OF-X-S Series Laser Fiber is a reusable (up to 10 uses) optical fiber delivery system designed to transmit laser energy from compatible laser sources to surgical treatment sites. The device utilizes high-purity quartz glass core technology with total internal reflection principles to deliver precise laser energy for various surgical applications.

The system features an SMA-905 standard connector for universal compatibility with cleared laser systems operating at wavelengths between 1940nm and 2100nm. Each fiber incorporates an integrated RFID module for usage tracking and cycle management, ensuring safe reuse within validated parameters.

The device is supplied non-sterile and requires sterilization prior to use. It is designed for professional use in healthcare facilities by physicians familiar with laser surgical procedures.

- **Indications for Use**

PT-OF-X-S Series Laser Fiber (Models PT-OF-A-S, PT-OF-B-S, PT-OF-C-S, PT-OF-D-S, PT-OF-E-S, PT-OF-F-S) is indicated for to deliver laser energy from a source to the target tissue in laser surgery applications, when used with any cleared/certified laser with wavelengths 1940nm - 2100nm equipped with SMA 905 standard connector.

- **Technological Characteristics Comparison**

Feature	Subject Device	Predicate Device	Comparison
Product name	PT-OF-X-S Series Laser Fiber	LGO- Surgical Laser Fibers	/
510(k) number	K253007	K243147	/
Manufacturer	Potent Medical	Light Guide Optics International Ltd.	/
Product code	GEX	GEX	Identical
Intended Use	PT-OF-X-S Series Laser Fiber (Models PT-OF-A-S, PT-OF-B-S, PT-OF-C-S,PT-OF-D-S, PT-OF-E-S, PT-OF-F-S) is indicated for to deliver laser energy from a source to the target tissue in laser surgery applications, when used with any cleared/certified laser with wavelengths 1940nm - 2100nm equipped with SMA 905 standard connector.	LGO-Surgical Laser Fibers are intended to be used to deliver the laser radiation to the target tissue when used with any cleared/certified laser with Operational wavelengths between 500 nm - 2200 nm equipped with SMA 905 standard or freestanding ferrule connector, as per the indications of the laser device used with.	Substantial Equivalence
Wavelength Range	1940nm - 2100nm	500nm - 2200nm	Similar, narrower range
Core Diameter	200μm - 1000μm	145μm - 1000μm	Similar range
Connector Type	SMA-905	SMA-905	Identical
Construction Materials	Silica quartz, hard clad, silicone, ETFE	Silica quartz, hard clad, silicone, polyimide, nylon, ETFE	Identical
Fiber Length	3 meters	Variable	Similar
Usage Type	Reusable (10x)	Single use or reusable (10x)	Same reuse capability

- **Performance Testing**

Standards Conformance: The subject device was tested according to recognized consensus standards including:

ISO 10993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process

ISO 10993-10: 2021 Biological evaluation of medical devices-Part 10: Tests for irritation and skin

sensitization

ISO 10993-23:2021 Biological evaluation of medical devices-Part 23: Tests for irritation

ISO 10993-11: 2017 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity

Non-Clinical Performance Testing: Comprehensive testing was conducted including:

- Optical Performance: Transmission efficiency, wavelength stability, beam profile analysis
- Mechanical Testing: Tensile strength, bend radius validation, bend fatigue test.
- Biocompatibility: Complete ISO 10993 evaluation for patient-contacting materials
- Reusability Testing: 10-cycle validation including mechanical and optical performance

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

- Substantial Equivalence Conclusion

The PT-OF-X-S Series Laser Fiber demonstrates substantial equivalence to the predicate device (K243147) based on the following:

Same Intended Use:

- Both devices deliver laser energy to target tissue for surgical applications
- Identical indications across multiple surgical specialties
- Same professional user population and clinical environment

Similar Technological Characteristics:

- Identical SMA-905 connector interface
- Same core construction materials and principles
- Equivalent optical transmission properties
- Similar mechanical performance specifications

Enhanced Features Without New Safety Concerns:

- RFID integration provides improved usage tracking capability

Performance Equivalence:

- Comprehensive non-clinical testing demonstrates equivalent performance
- Identical reuse validation parameters

Minor differences in wavelength range specification and RFID integration do not raise new questions of safety or effectiveness. The device operates within well-established technological parameters and provides equivalent clinical functionality to the predicate device.

Based on the comparison of intended use, technological characteristics, and performance data, the PT-OF-X-S Series Laser Fiber is substantially equivalent to the identified predicate device.