



November 4, 2025

menovex Medical Technology (Shenzhen) Co., Ltd
% Kyra Kang
Official Correspondent
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room1308, Baohua International Plaza, West Guangzhong Road
Jingan District
Shanghai,
China

Re: K251303

Trade/Device Name: Tamburo Thulium Fiber Laser System;

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: October 30, 2025

Received: October 30, 2025

Dear Kyra Kang:

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/pmnmn.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](https://www.fda.gov/training-and-continuing-education/cdrh-learn)) 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: 2025.11.04
19:43:58 -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

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.

K251303

?

Please provide the device trade name(s).

?

Tamburo Thulium Fiber Laser System

Please provide your Indications for Use below.

?

The Tamburo Thulium Fiber Laser System are 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.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) Summary

I. Submitter

menovex Medical Technology (Shenzhen) Co., Ltd
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Jinsha Community, Kengzi Street, Pingshan District, Shenzhen 518118, China
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Preparation date: April 27, 2025

Submission Correspondent

Ms. Kyra Kang
Landlink Healthcare Technology (Shanghai) Co., Ltd.
E-mail: kyra.kang@landlink-health.com

II. Proposed Device

Device Trade Name:	Tamburo Thulium Fiber Laser System
Common name:	powered laser surgical instrument
Regulation Number:	21 CFR 878.4810
Regulatory Class:	Class II
Product code:	GEX
Review Panel:	General & Plastic Surgery

III. Predicate Devices

510(k) Number:	K183647
Trade name:	SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories).
Common name:	powered laser surgical instrument
Classification:	Class II
Product Code:	GEX
Manufacturer	General & Plastic Surgery

IV. Device description

Tamburo Thulium Fiber Laser System are 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 Tamburo is a Thulium fiber laser device emitting at a wavelength of 1940 nm, which is used by physicians as a tool in surgical procedures.

This device consists of a thulium laser, footswitch, power cord, Interlock connector, ground wire and protective goggles.

The thulium laser includes thulium laser, cooling device, aiming beam device, and LCD touch screen.

Tamburo Thulium Laser Fiber:

Tamburo Thulium Laser Fibers are delivery devices that transmit laser energy from the laser console to the treatment site through the fiber tip. The laser connector secures the device to the laser.

This device consists of a fiber, dust cap, ferrule, outer cap and handle.

The fiber includes core, cladding, coating and outer jacket.

Tamburo Thulium Laser Fibers are compatible for use with Tamburo Thulium Laser Systems.

V. Indications for use

The Tamburo Thulium Fiber Laser System are 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.

VI. Comparison of technological characteristics with the predicate devices

The comparison and discussion between the subject device and the predicate devices are listed in below table

Table 5.1 General Comparison

Characteristics	Proposed device	Predicate device (K183647)	Discussion
Trade name	Tamburo Thulium Fiber Laser System	SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium	/

		SuperPulsed Laser, SOLTIVE™ Laser Fibers, and Accessories).	
Classification Name	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology	Same
Product Code	GEX	GEX	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Same
Indications for use	The Tamburo Thulium Fiber Laser System are 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
Laser Source	Thulium laser	Thulium laser	Same
Wavelength	1938.9nm(1940 ±20 nm)	1936.5nm(1940 ±20 nm)	Same

Laser mode	Pulsed / CW	Pulsed	Different 1
Divergence angle of terminal laser beam	15.40° (16°±20%)	12.96°	Different 2
Aiming beam peak wavelength	522.55nm (520 ±10nm)	518.50nm (500-550nm)	Similar
Frequency	Up to 2400 Hz	Up to 2400 Hz	Same
Pulse Energy	0.025-6J	0.025-6J	Same
Pulse duration	0.2-50ms	0.2-50ms	Same
Max average power	60W	60W	Same
Delivery system	Optical fibers	Optical fibers	Same
Cooling system	Air cooling system	Air cooling system	Same
Fiber size	150, 200, 272, 365, 550, 800µm	150, 200, 365, 550, 940 µm	Similar
Fiber Sterilization	EO	EO	Same

Analysis 1 Laser mode

Both pulsed and CW modes have been rigorously tested and validated to ensure they meet all applicable regulatory requirements and deliver consistent, reliable performance. The difference in laser mode does not affect the safety or effectiveness.

Analysis 2 Divergence angle of terminal laser beam

By calculation, the distance of the Tamburo laser is 0.84 times that of Olympus. During clinical use, the fiber directly contacts the tissue. The distance difference can be ignored. The device has been rigorously tested and validated to ensure that it meets all applicable safety and performance standards, demonstrating that the divergence angle does not affect its ability to deliver effective and controlled laser energy for its intended use. Therefore, this difference does not pose any risk to the safety or effectiveness of the device.

VII. Non-Clinical Testing

The device described in this summary, were tested and demonstrated to be in conformance with the following standards:

Performance testing :

A comprehensive performance test was conducted on the Tamburo Thulium Fiber Laser System and Tamburo Thulium Laser Fiber to verify the performance of the product in optical, mechanical and Hardware aspects, along with comparative testing against equivalent products to demonstrate substantial equivalence.

Biocompatibility testing

Biocompatibility of the device was evaluated in accordance with the FDA guidance "Use of International Standard ISO 10993-1" The following testing was conducted:

- ISO 10993-1 Fifth edition 2018-08
- ISO 10993-5 Third edition 2009-06-01
- ISO 10993-10 Fourth edition 2021-11
- ISO 10993-11 Third edition 2017-09

- ISO 10993-23 **Software First edition 2021-01**

Guidance for Industry and Food and Drug Administration Staff-Content of Premarket Submissions for Device Software Functions

Electrical Safety and EMC

- IEC 60601-1 Edition 3.2 2020-08
- IEC 60601-1-2 Edition 4.1 2020-09
- IEC 60601-4-2 Edition 1.0 2-2024-03
- IEC 60601-1-6 Edition 3.2 2020-07
- IEC 60601-2-22 Edition 4.0 2019-11

Shelf -life

The shelf life of the Tamburo Thulium Fiber Laser System is ensured by the stability evaluation performed in both real time and accelerated conditions, by the stability of laser performance. The performance is maintained after transport simulation and after 7 years aging.

The shelf life of the Tamburo Thulium Laser Fiber is set to 3 years. The sterile barrier performance (with the sterile barrier manufactured at validated worst case manufacturing conditions) is maintained after transport simulation and after 3 years aging (corresponding to the shelf-life of the device).

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.