July 21, 2026

Rhein Laser Technologies Co., Ltd.
Na Wu
Quality Manager
801,8f, E2 Bldg., Future City, #999 High-Tech Ave., E. Lake High-Tech Development Zone, Wuhan 430206, China (Free Trade Zone Wuhan Area)
Wuhan, 430206
China

Re: K261738
Trade/Device Name: Medical Thulium Fiber Laser Systems (UroFiber 150Q)
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: May 26, 2026
Received: May 27, 2026

Dear Na Wu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.07.21 21:06:28 -04'00'

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261738

Please provide the device trade name(s).

Medical Thulium Fiber Laser Systems (UroFiber 150Q)

Please provide your Indications for Use below.

Medical Thulium Fiber Laser Systems （UroFiber 150Q） is intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

Rhein Laser Technologies Co., Ltd.

510(k) Summary

Medical Thulium Fiber Laser Systems

Date of Summary Modification: July 3rd, 2026

1. Applicant Information

Rhein Laser Technologies Co., Ltd.
801,8F, E2 Building, Future City, No.999 High-Tech Avenue, East Lake High-Tech Development Zone, Wuhan 430206, China (Free Trade Zone Wuhan Area)
Contact Person: Na Wu
Title: Quality Manager
Telephone Number: +86-027-65279157
Email: na.wu@rheinlaser.com

2. Proposed Device

Trade Name: Medical Thulium Fiber Laser Systems (UroFiber 150Q)

Common Name:	Powered Laser Surgical Instrument
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Model(s):	UroFiber 150Q
Classification Regulation Number:	21 CFR 878.4810
Product Code:	GEX (Powered Laser Surgical Instrument)
Device Class:	II
Review Panel:	General & Plastic Surgery

3. Predicate Device 1

510(k) Number:	K253100
Applicant:	Asclepion Laser Technologies Gmbh
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Trade Name:	MultiPulse TFL

4. Predicate Device 2

510(k) Number:	K133891
Applicant:	Asclepion Laser Technologies Gmbh
Classification Name:	Laser surgical instrument for use in general and

plastic surgery and in dermatology

Trade Name: MULTIPULSE TM+1470

5. Device Description

Medical Thulium Fiber Laser Systems (UroFiber 150Q) consists of a host (including a power supply, thulium fiber laser, safety control module, cooling module), foot switch and optical fiber (single use, sterilized by the user before use. Model:RL-200, RL-272, RL-365, RL-550, RL-800, RL-1000, specification: 300)composition. Protective glasses not included.

6. Indications for Use

Medical Thulium Fiber Laser Systems (UroFiber 150Q) is intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

7. Comparison to the Predicate Devices

Indications for Use/Intended Use:

The indications for use of the Medical Thulium Fiber Laser Systems (UroFiber 150Q) are within those of the predicate devices.

Technological Characteristics:

The Medical Thulium Fiber Laser Systems (UroFiber 150Q) has the same intended use, principle of operation and technical characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate devices do not raise any issues of safety or efficacy.

Performance data supports that the device is as safe and effective as the predicate devices for its intended use.

Table 1 Comparison between UroFiber 150Q and the Predicate Devices

Feature	Proposed Device	Predicate device 1 (K253100)	Predicate Device 2 (K133891)	Remarks
Manufacturer	Rhein Laser Technologies Co., Ltd.	Asclepion Laser Technologies Gmbh	Asclepion Laser Technologies Gmbh	/
Device Name	Medical Thulium Fiber Laser Systems	MultiPulse TFL	MULTIPULSE TM+1470	/
Model(s)	UroFiber 150Q	/	/	/
Laser Source	Thulium Laser	Thulium Laser	Thulium Laser	Same
Wavelength	1940 nm	1940 nm	1940 nm and 1470 nm	Same
Emission	CW/Pulsed	CW/Pulsed	CW/Pulsed	Same
Pulse Width	CW or 0.1 to 15 ms	CW or 0.1 to 12 ms	CW or 0.5 to 750 ms	Within Predicate Devices
Frequency	2500 Hz	2500 Hz	2500 Hz	Same
Max Average Power	150 W	200 W	150 W	Within Predicate Devices
Fiber core diameter	200 – 1000 µm	200 – 1000 µm	200 – 1000 µm	Same

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Electrical safety and electromagnetic compatibility (EMC)
The proposed device complies with the following recognized consensus standards:

- AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

- IEC 60601-1-2:2014+AMD1:2020 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

Laser Safety
Testing was conducted to demonstrate that the proposed device complies with the following standards:

- IEC 60825-1:2014 Safety of Laser Products - Part 1: Equipment Classification and Requirements

- IEC 60601-2-22:2019 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Biocompatibility testing
Biocompatibility evaluation for the Optical Fibers after sterilization was conducted in accordance with the FDA Guidance "Use of International Standard ISO-10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process'" September 2023. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

The optical fibers are considered tissue contacting for a duration of less than 24 hours.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software documentation level for this device was determined to be "basic."

Specification Testing

Testing was conducted to validate that the proposed device meets design specifications for wavelength, pulse width, pulse energy, frequency, and maximum average power.

9. Conclusions

The above performance testing supports that the Medical Thulium Fiber Laser Systems (UroFiber 150Q) is as safe and as effective as the predicate devices currently marketed for the same intended use.