Novembeer 19, 2024

Rhein Laser Technologies Co., Ltd.
Na Wu
Quality Manager
801,8F, E2 Building, Future City, No.999 High-Tech Avenue,
East Lake High-Tech Development Zone
Wuhan, 430206
China

Re: K242293
Trade/Device Name: Medical Thulium Fiber Laser System (UroFiber 60Q)
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: August 2, 2024
Received: August 2, 2024

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 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: 2024.11.19 21:33:57 -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242293

Device Name
Medical Thulium Fiber Laser System (UroFiber 60Q)

Indications for Use *(Describe)*
Medical Thulium Fiber Laser System (UroFiber 60Q) 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.

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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Rhein Laser Technologies Co., Ltd.

510(k) Summary

Medical Thulium Fiber Laser System (UroFiber 60Q)

Date of Summary Preparation: August 01, 2024
Date of Summary Modification: November 15, 2024

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 System (UroFiber 60Q)
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Model(s):	UroFiber 60Q
Classification Regulation Number:	21 CFR 878.4810
Product Code:	GEX (Powered Laser Surgical Instrument)
Device Class:	II
FDA CDRH Review Panel:	General & Plastic Surgery

3. Predicate Device(s)

510(k) Number:	K210142
Applicant:	Quanta System Spa
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Trade Name:	Fiber Dust

This predicate has not been subject to a design-related recall.

4. Reference Device(s)

510(k) Number:	K183647

Rhein Laser Technologies Co., Ltd.

Applicant:	Olympus Surgical Technologies America
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Trade Name:	SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE™Laser Fibers, and Accessories)

5. Device Description

Medical Thulium Fiber Laser System (UroFiber 60Q) consists of a host (including a power supply, thulium fiber laser, safety conrol module, cooling module), foot switch and optical fiber (disposable use, sterilized by the user before use. Model: RL-150, 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 System (UroFiber 60Q) is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissuewith or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.

7. Comparison to the Predicate Device(s)

Indications for Use/Intended Use:

The subject Medical Thulium Fiber Laser System (UroFiber 60Q) is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissuewith or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery, while the predicate device (K210142, Fiber Dust) 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. All devices share the same application and the same 1940 nm laser wavelengath for treatment.

8. Technological Characteristics: The subject Medical Thulium Fiber Laser System (UroFiber 60Q) has the same intended use, principle of operation and technical characteristics as the predicate/reference devices. Performance data supports that the device is as safe and effective as the predicate/reference devices for its intended use.

Table 1 Comparison between UroFiber 60Q and the Predicate/Reference Devices

Rhein Laser Technologies Co., Ltd.

Feature	Proposed Device	Predicate Device (K210142)	Reference Device (K183647)	Remarks
Manufacturer	Rhein Laser Technologies Co., Ltd.	Quanta System Spa	Olympus Surgical Technologies America	
Device Name	Medical Thulium Fiber Laser Systems	Fiber Dust	SOLTIVE™ Laser System	
Model(s)	UroFiber 60Q	Not Specified	Not Specified	
Intended Use	Medical Thulium Fiber Laser System (UroFiber 60Q) is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissuewith or without an endoscope, in the following indications: urology, lithotripsy, gastroenterological surgery and gynecological surgery.	The predicate device (**K210142**) ***Fiber Dust*** 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.	The reference device (**K183647**) ***SOLTIVE™ Laser System*** 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	Thulium Laser	Same
Wavelength	1940 nm	1940 nm	1940 nm	Same
Emission	CW/Pulsed	CW/Pulsed	CW/Pulsed	Same
Aiming Beam	532 nm	532 nm	500～550 nm	Same
Pulse Width	0.1 to 15 ms	0.1 to 15 ms	0.2 to 50 ms	Same
Pulse Energy	0.02～6 J	0.02～6 J	0.025～6 J	Same
Frequency	1～2500 Hz	1～2500 Hz	1～2400 Hz	Same
Max Average Power	60 W	60 W	60 W	Same
Cooling System	Air Cooling	Air Cooling	Air Cooling	Same

8. Performance Data

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

The proposed device performs testing in accordance with the following recognized consensus standards:

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020 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

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

ISO10993-10 Fourth edition 2021-11:Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

ISO10993-5: 2009 Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity and found to be biocompatible

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

ISO 10993-4: 2017 Biological evaluation of medical devices -Part 4: Selection of tests for interactions with blood

9. Clinical/Animal Testing

The information included in this premarket notification included the following: product code, regulation number, device class , controls, indications for use, wavelength，laser source，emission，aiming beam，pulse width，pulse width，pulse energy，frequency，maximum average power，cooling system，delivery system, software, delivery devices and electromagnetic compatibility and electrical safety compliance, and the non-clinical tests complied with the requirements of relevant recognized standards. The proposed Medical Thulium Fiber Laser System (UroFiber 60Q) device is not considered to need new animal or clinical testing.

10. Conclusions

Based on the above performance as documented in this application, the Medical

Thulium Fiber Laser System (UroFiber 60Q) is found to have a safety and effectiveness profile that is similar to the predicate/reference devices.