December 17, 2024

Allengers Global Healthcare Private Limited
Harpreet Singh
Director-Technical
Room No.5, Khasra no. 79, Bhankarpur, Mubarakpur Road
District- Mohali
Derabassi, Punjab 140507
India

Re: K242987
Trade/Device Name: Thulium Fiber Laser (FiberLAZE+, FiberLAZE)
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 19, 2024
Received: September 26, 2024

Dear Harpreet Singh:

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: 2024.12.17 21:57:32 -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.

Submission Number *(if known)*

K242987

Device Name

Thulium Fiber Laser (FiberLAZE+, FiberLAZE)

Indications for Use *(Describe)*

Thulium Fiber Laser is intended for incision, excision, resection, ablation, vaporization, coagulation, and haemostasis of soft tissue in the following indications: Urology, Lithotripsy, Gastroenterological surgery and Gynecological Surgery.

Urology

- Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]
- Laser Resection of the Prostrate (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 Indications

- 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 of the 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

(K242987)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92

Applicant /Manufacturer Name and Address	**Allengers Global Healthcare Private Limited** Room No.5, Khasra no. 79, Bhankarpur, Mubarakpur Road, Derabassi, District- Mohali, 140507, Punjab (India) +911762-272600
510(K) Contact person	**Harpreet Singh** **Address:** Room No.5, Khasra no. 79, Bhankarpur, Mubarakpur Road, Derabassi, District- Mohali, 140507, Punjab (India) **Contact Number:** +919876615337 **Email ID:** ra@allengersglobal.com;director@allengersglobal.com
Date Prepared	15 September,2024
Device/Trade Name	Thulium Fiber Laser
Models Names	FiberLAZE^{+}, FiberLAZE
Regulation Class	Class II
Regulation Name	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation Number	21 CFR 878.4810
Product Code	GEX
Panel	General and Plastic Surgery
Predicate Device	Fiber Dust (K210142) -Quanta system SpA
Reference Device	Soltive Laser System(K183647)-Olympus Surgical Technologies America

Device Description

Thulium Fiber Laser is a laser system that emits a wavelength of 1.94 μm with a laser output power up to 60W and 35W respectively. Laser radiation is delivered to the patient via an optical fiber.

The main subsystems of the device are the laser, the power electronics, the optical delivery system, the control electronics, and the cooling system. Software controls the device functions and allows the user select device settings. Laser emission is triggered by a footswitch.

Accessories

The device is intended to be used together with delivery optical fiber that separately received a FDA clearance for an intended use.

Intended Use/ Indications for Use:

Thulium Fiber Laser is intended for incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue in the following indications: Urology, Lithotripsy,Gastroenterological surgery and Gynecological Surgery.

Urology

- Ablation of Benign Prostatic Hyperplasia (Hypertrophy) [BPH]
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- 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

Comparison with predicate device

The subject device technological characteristics and indication for use are same to the predicate device. Other differences between the subject device and predicate device not raise new types of question regarding the subject device's safety and efficacy.

Summary of Technical Characteristic

Feature	**Subject Device**		**Predicate Device**	**Justification for differences**
Manufacturer	**Allengers Global Healthcare Pvt. Ltd.**		**Quanta System SpA**	
Models	FiberLAZE^{+}	FiberLAZE	Fiber Dust	NA
510(k)	K242987		Fiber Dust (K210142)	NA
Manufacturer	Allengers Global Healthcare Pvt. Ltd.		Quanta System SpA	NA
Device Name	Thulium Fiber Laser		Fiber Dust	NA
Laser Medium	Thulium Laser		Thulium Laser	Same
Wavelength	1.94 μm		1.94 μm	Same
Emission	Pulsed/CW		Pulsed/CW	Same
Pulse Duration	0.1 to 15ms		0.1 to 15ms	Same
Pulse Frequency	1 to 2500 Hz	1 to 1600 Hz	1 to 2500 Hz	Similar
Pulse Energy	0.02 to 6J		0.02 to 6J	Same
Maximum Average Power	60 W	35W	60 W	Similar
Delivery System	Optical Fiber		Optical Fiber	Same
Aiming Beam				
Type	DPSS		DPSS	Same
Power	Power <5mW		Power <5mW	Same
Wavelength	Wavelength 532nm		Wavelength 532nm	Same
Laser Class	Class 3R		Class 3R	Same

Performance Testing

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

- Risk analysis activities, in compliance with the requirements of ISO 14971: 2019 Medical devices - Application of Risk Management to Medical Devices.
- Electrical and laser safety and electromagnetic compatibility tests, in compliance with:
  - IEC 60601-1:2005+A1:2012+A2:2020 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
  - IEC 60601-1-2:2014+A1:2020, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility - 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.
  - IEC 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements.
  - IEC 60601-1-6:2010+A1:2013+A2:2020 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance-collateral standard: Usability.
  - IEC 62366-1:2015/AMD1:2020 Medical devices - Part 1: Application of usability engineering to medical devices

- Software verification and validations, in compliance with FDA "**Content of Premarket Submissions for Device Software Functions"** (issue on 2023). The tests verified that the subject Thulium Fiber Laser performs according to its specifications.

Conclusion

The Thulium Fiber Laser does not introduce any new indications for use, nor does the use of the systems result in any new potential hazard. The Thulium Fiber Laser, the subject device is substantially equivalent to the predicate device Fiber Dust (K210142).

The intended use, the design principle, and the applicable standards for the subject device are identical to those of the predicate. Some characteristics, for example, their appearance, user interface and the physical dimension are different. However performance test result demonstrates that these differences do not raise any new question of safety and effectives. Therefore, it is Allengers Global Healthcare Pvt. Ltd. opinion that the subject device appears to be as safe and effective as the predicate device.