October 23, 2025

Asclepion Laser Technologies GmbH
Francesco Dell'antonio
RA Consultant
Bruesseler Strasse 10
Jena, 07745
Germany

Re: K253100
Trade/Device Name: MultiPulse TFL
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 8, 2025
Received: September 24, 2025

Dear Francesco Dell'antonio:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.10.23 10:33:09 -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

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)*

K253100

Device Name

MultiPulse TFL

Indications for Use *(Describe)*

MultiPulse TFL Laser system and its fibre optic delivery system are 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.

Urology
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
Urethral Strictures
Bladder Neck Incisions (BNI)
Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors Ablation of Benign Prostatic Hypertrophy (BPH)
Transurethral incision of the prostate (TUIP)
Laser Resection of the Prostate Laser Enucleation of the Prostate
Laser Ablation of the Prostate
Condyloma
Lesions of external genitalia
Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi
Treatment of distal impacted fragments remaining in the ureters following lithotripsy
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 hemostasis) including: Appendectomy, Polyps, Biopsy, Gall Bladder calculi, Biliary/ Bile duct calculi, Ulcers, Gastric ulcers, Duodenal ulcers, Non Bleeding Ulcers, Pancreatitis, Hemorrhoids, Cholecystectomy, Benign and Malignant Neoplasma, Angiodysplasia, Colorectal cancer, Telangiectasia, Telangiectasia of the Osler-WeberRenu disease, Vascular Malformation, Gastritis, Esophagitis, Esophageal ulcers, Varices, Colitis, Mallory-Weiss tear, Gastric Erosions.

Arthroscopy
Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) including: Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including: Percutaneous Laser Disc Decompression/Discectomy, Foraminoplasty, Ablation and coagulation of soft vascular and nonvascular tissue in minimally invasive spinal surgery.

Gynecology
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization,

coagulation and hemostasis) of soft tissue: Intra-uterine treatment of submucous fibroids, benign endometrial polyps and uterine septum by incision, excision, ablation and/or vessel coagulation, Soft tissue excision procedures such as excisional conization of the cervix.

ENT
Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including: Endonasal/sinus Surgery, Partial turbinectomy, Polypectomy, Dacryocystorhinostomy, Frontal Sinusotomy, Ethmoidectomy, Maxillary antrostomy, Functional endoscopic sinus surgery, Lesions or tumors (oral, nasal, glossal, pharyngeal and laryngeal), Tonsillectomy, Adenoidectomy.

General surgery
Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: Cholecystectomy, Lysis of adhesion, Appendectomy, Biopsy, Skin incision, Tissue dissection, Excision of external tumors and lesions, Complete or partial resection of internal organs, tumors and lesions, Mastectomy, Hepatectomy, Pancreatectomy, Splenectomy, Thyroidectomy, Parathyroidectomy, Herniorrhaphy, Tonsillectomy, Lymphadenectomy, Partial Nephrectomy, Pilonidal Cystectomy, Resection of lipoma, Debridement of Decubitus Ulcer, Hemorrhoids, Debridement of Statis Ulcer.

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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K253100

Applicant / Manufacturer Name and Address:	Asclepion Laser Technologies GmbH Bruesseler Strasse 10, 07745 Jena - Germany
510(k) Contact Person:	Mr. Francesco Dell'Antonio Regulatory Consultant E-Mail: francesco.dellantonio@asclepion.com
Date Prepared:	8th September 2025
Trade Name:	MultiPulse TFL
Common Name:	MultiPulse TFL
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Main Predicate Device	MULTIPULSE TM+1470 (K133891), Asclepion Laser Technologies GmbH
Reference Device	Fiber Dust PRO (K220426), Quanta System Spa CYBER TM 200 (K131081), Quanta System Spa

Performance Standards:
There are no mandatory performance standards for this device.

Description of the device:
The MultiPulse TFL laser system and its fiber optic delivery system is a laser Class IV, operating in CW or pulsed mode at a wavelength of 1940 nm. The laser power up to 200W is transmitted through different optical fibers. Besides of the optical bench the device consists of a power supply, a water cooling unit and a control electronic. The device is operated by a touch screen and a foot switch.

Description of the modifications:
The subject device is a modification to previously cleared MultiPulse TM+1470 due to some technical modifications concerning laser emission parameters and the related controlling software and hardware.
The subject device and the predicate device have the differences shown in the table below:

	Main Predicate Device	**Subject device**
Device name	MULTIPULSE TM+1470	MultiPulse TFL
510k number	K133891	-

Wavelength	1940 um and 1470um	1940 um
Power max.	150W	200W
Pulse Duration	CW or up to 750ms	CW or up to 12 ms

Additional reference devices were considered in the substantial equivalence discussion, to justify why the differences do not raise any concern about safety and efficacy.

The subject device has the same intended use of the unmodified device. Moreover, the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

Based on the nature of the changes implemented, the device underwent and successfully passed performance testing and software verifications and validation according to the relevant standards.

Intended Use:

MultiPulse TFL Laser system and its fibre optic delivery system are 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.

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- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors Ablation of Benign Prostatic Hypertrophy (BPH)
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostate Laser Enucleation of the Prostate
- Laser Ablation of the Prostate
- Condyloma
- Lesions of external genitalia
- Endoscopic fragmentation of urethral, ureteral, bladder, and renal calculi
- Treatment of distal impacted fragments remaining in the ureters following lithotripsy
- 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

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Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: Appendectomy, Polyps, Biopsy, Gall Bladder calculi, Biliary/Bile

duct calculi, Ulcers, Gastric ulcers, Duodenal ulcers, Non Bleeding Ulcers, Pancreatitis, Hemorrhoids, Cholecystectomy, Benign and Malignant Neoplasma, Angiodysplasia, Colorectal cancer, Telangiectasia, Telangiectasia of the Osler-WeberRenu disease, Vascular Malformation, Gastritis, Esophagitis, Esophageal ulcers, Varices, Colitis, Mallory-Weiss tear, Gastric Erosions.

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Technological Characteristics Comparison

Specification	Main Predicate device	Additional predicate device	Additional predicate device	Subject device
Trade/Device Name	**MULTIPULSE TM+1470**	**Fiber Dust PRO**	**CYBER TM 200**	**MultiPulse TFL**
Submitter	Asclepion Laser Technologies Gmbh	Quanta System Spa	Quanta System Spa	Asclepion Laser Technologies Gmbh
510(k) number	K133891	K220426	K131081	-
Wavelength	1940 um and 1470um	1940 um	2010 um	1940 um
Power, max.	150W	60W	200W	200W
Pulse Duration	CW or up to 750ms	CW or up to 15ms	CW or up to 75ms	CW or up to 12 ms
Repetition rate, max	2500 Hz	2500 Hz	100 Hz	2500 Hz
Delivery system	Optical fiber (single use and reusable)	Optical fiber (single use and reusable)	Optical fiber (single use and reusable)	Optical fiber (single use and reusable)

Non clinical Performance Data:

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

- IEC 60601-1:2005/A1:2012/AMD:2020: Medical electrical equipment – Part 1: General requirements for safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 62304: Medical Device Software – Software life cycle processes
- IEC 62366-1: Medical devices – Application of usability engineering to medical devices
- IEC 60601-2-22:2019 Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- ISO 14971:2019 Medical devices – Application of risk management to medical devices
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions".

MultiPulse TFL passed all the required testing and is in compliance will all applicable sections of the abovementioned performance standards.

Biocompatibility:

The biocompatibility of MultiPulse TFL is established based on the predicate devices.

Comparison with predicate device:

The subject and predicate devices have the same intended use and the same fundamental scientific technology. Any minor difference does not raise concern about safety and effectiveness.

Conclusions

The differences between the subject and predicate device do not raise new types of questions regarding safety and effectiveness, and the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.