



February 22, 2024

Asclepion Laser Technologies GmbH
Tom Gruender
Regulatory Affairs Manager
Bruesseler Strasse 10
Jena, Thuringia 07747
Germany

Re: K231876

Trade/Device Name: MultiPulse HoPLUS

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, GCJ

Dated: June 26, 2023

Received: June 26, 2023

Dear Tom Gruender:

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.

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,

Jianting Wang
-S



Digitally signed by Jianting Wang -S
Date: 2024.02.22 15:36:05 -05'00'

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

510(k) Number (if known)

K231876

Device Name

MultiPulse HoPLUS

Indications for Use (Describe)

Laser Device:

The MultiPulse HoPLUS Laser system and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery.

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 (BHP)

Transurethral incision of the prostate (TUIP)

Holmium Laser Resection of the Prostate (HoLRP)

Holmium Laser Enucleation of the Prostate (HoLEP)

Holmium laser Ablation of the Prostate (HoLAP)

Condylomas

Lesions of external genitalia

Lithotripsy and Percutaneous Urinary Lithotripsy

Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate

Dehydrate stones

Endoscopic fragmentation of kidney 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

Telangiectasias

Telangiectasias of the Osler-Weber-Renu 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) in small and large joints of the body, excluding the spine but including:

Ligament and tendon Release

Contouring and sculpting of articular surfaces

Capsulectomy in the knee

Chondroplasty in the knee

Debridement of inflamed synovial tissue

Chondromalacia Ablation

Chondromalacia and tears

Plica Removal

Meniscectomy

Loose Body Debridement

Lateral retineacular release

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including

Percutaneous Laser Disc Decompression/Discectomy of the L4-5 and L5-S1 lumbar discs, including Foraminoplasty

Percutaneous Cervical Disc Decompression/Discectomy Percutaneous Thoracic Disc Decompression/Discectomy

Pulmonary

Open and endoscopic pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue)

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) of soft tissue

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and cartilage) including:

Endonasal / sinus Surgery

Partial turbinectomy

Polypectomy

Dacryocystorhinostomy

Frontal sinustomy

Ethmoidectomy

Maxillary antrostomy

Functional endoscopic sinus surgery

Dermatology and Plastic Surgery

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

Basal Cell Carcinomas

Lesions of skin and subcutaneous tissue

Skin tags
Plantar warts
Lesions of skin and subcutaneous tissue
Port Wine Stains
Papillomas

General Surgery

Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Appendectomy

Skin incision

Excision of external and internal lesions

Complete or partial resection of internal organs, tumors and lesions

Biopsy

Morcellator:

The MultiCut Solo Morcellator is intended for use under endoscopic visualization for the transurethral mechanical morcellation and removal of the adenoma after enucleation of the prostate during endoscopic surgical procedures in urology.

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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