DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 31, 2017

Asclepion Laser Technologies Gmbh
Antje Katzer
RA Manager
Bruesseler Str. 10
Jena, 07747 DE

Re: K161257
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
Dated: October 4, 2016
Received: October 6, 2016

Dear Antje Katzer:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161257

Device Name

MultiPulse HoPLUS

Indications for Use *(Describe)*

The MULTIPULSE HoPLUS Laser system and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic, to perform incision, ex-cision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Sur-gery.
Typical Applications:

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)
• Holmiurm 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
• Chondreoplasty 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-SI lumbar discs, including Forminoplasty
• Percutaneous Cervical Disc Decompression/Discectomy
• Percutaneous Thoracic Disc Decompression/Discectomy

Pulmonary
Open and endoscopic pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue)
Gynecology
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) 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 lesions
• Complete or partial resection of internal organs, tumors and lesions
• Biopsy

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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Asclepion Laser Technologies GmbH · Brüsseler Str. 10 · 07747 Jena · Germany

SPECIAL 510(k) SUMMARY
ASCLEPION LASER TECHNOLOGIES GmbH
MultiPulse HoPlus

This Special 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH MultiPulse HoPLUS is submitted in accordance with the requirements of 21 CFR 807.92 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant:	ASCLEPION LASER TECHNOLOGIES GmbH Bruesseler Str. 10 07747 Jena, Germany
Contact Person:	Mrs. Antje Katzer Product Management and International Regulatory Affairs
Phone: Fax: e-mail:	+49 3641 77 00 309 +49 3641 77 00 302 antje.katzer@asclepion.com
Preparation Date:	March 29, 2017
Device Name:	MultiPulse HoPLUS
Common Name:	Surgical Holmium-Laser
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology GEX 21 CFR 878.4810

Equivalent Devices:	MultiPulse HoPLUS	K131987	Asclepion Laser Technologies
	Lumenis Pulse 120	K140388	Lumenis

Device Description: The MultiPulse HoPLUS Laser system and its fiber optic delivery system is a laser Class IV, pulsed, solid state Holmium-YAG, which emits laser radiation with a wavelength of approximately 2100 nm with a pulse with between 150-1700 microseconds. The laser power up to 140 Watts is transmitted to the tissue through different optical fibers.

The laser system consists of:
Laser system including control panel (user interface)
Foot switch
A variety of application fibers and accessories

Intended Use: 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.

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Bladder Neck Incisions (BNI)
Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors
Ablation of Benign Prostatic Hypertrophy (BHP)
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Holmium Laser Resection of the Prostrate (HoLRP)
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Dehydrate stones
Endoscopic fragmentation of kidney 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
Telangiectasias
Telangiectasias of the Osler-Weber-Renu disease
Vascular Malformation
Gastritis
Esophagitis
Esophageal ulcers
Varices
Colitis
Mallory-Weiss tear
Gastric Erosions

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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:
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Chondromalacia and tears
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Partial turbinectomy
Polypectomy
Dacryocystorhinostomy
Frontal sinustomy
Ethmoidectomy
Maxillary antrostomy
Functional endoscopic sinus surgery

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

General Surgery
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Appendectomy
Skin incision
Excision of external and internal lesions
Complete or partial resection of internal organs, tumors and lesions
Biopsy

Summary of Technical Characteristics

	Proposed Modified Device	**Un-Modified Predicate Device**	**Un-Modified Predicate Device**
Name 510(k)	MultiPulse HoPLUS Model 1911	Multipulse Holmium Plus Model 1910 K131987	Lumenis Pulse 120H K140388
Indications	Incision, excision, resection, ablation, vaporisation, coagulation and hemostasis in medical specialties	Incision, excision, resection, ablation, vaporisation, coagulation and hemostasis in medical specialties	Incision, excision, vaporization, ablation and coagulation in medical specialties
Device Type	Ho :YAG	Ho :YAG	Ho :YAG
Delivery	Different flexible Quartz/Quartz fibers Reusable and single use	Different flexible Quartz/Quartz fibers Reusable and single use	Different flexible Quartz/Quartz fibers Reusable and single use
Wavelength	2100 nm	2100 nm	2100 nm
Average Power	140 Watt	110 Watt	120 Watt
Energy range	0,25 – 6 Joule	0,3 - 3,5 Joule	0,2 - 6 Joule
Pulse Duration	150 – 1700 µs	200-800 µs	adjustable
Repetition Rate	5 – 100 Hz	Up to 75 Hz	5 - 80 Hz
Power supply	400 V 50 Hz/16 A 3-phase	230V 50Hz/32A monophase	230V 50Hz/<46 A monophase
Weight	285 kg	240 kg	245 kg
Dual pedal footswitch	Yes	Yes	Yes

Comparison to: The MultiPulse HoPLUS, model 1911, surgical laser and delivery devices share the same intended use, similar design features, functional features, and therefore, is substantially equivalent to the Asclepion MultiPulse HoPLUS, model 1910.
The Multipulse HoPlus is also substantial equivalent in terms of indications for use to the Lumenis Pulse 120H system with similar parameters and the same intended use.

Non-clinical Performance Data: Verification and Validation activities. These activities comprises the verification and validation of the software, the verification of the device, the verification of the fiber, the verification of the laser, an Investigation Report and the Final Test Report. These investigations lead to the conclusion, that the device is as safe and effective as the predicates and no additional risks occur.

Clinical Performance Data: None

Conclusion: The Multipulse HoPLUS, model 1911, as a modification of the MultiPulse HoPLUS, model 1910, is substantially equivalent to the cited legally marked predicate devices.