January 18, 2023

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

Re: K213597
Trade/Device Name: MultiCut Solo
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 14, 2022
Received: December 19, 2022

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213597

Device Name
MultiCut Solo

Indications for Use *(Describe)*
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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5. 510(K) SUMMARY

Applicant / Manufacturer Name and Address:	Asclepion Laser Technologies GmbH Bruesseler Strasse 10 07745 Jena Germany
510(k) Contact Person:	Tom Gruender Regulatory Affairs Manager Asclepion Laser Technologies Email: tom.gruender@asclepion.com Phone: +49-03641-7700 201 Fax: +49-03641-7700 102
Date Prepared:	13th January 2023
Common Name:	Soft Tissue Morcellator and Accessories
Device Name:	MultiCut Solo
Regulatory Class:	Class II
Regulation Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	GCJ
Basis for Submission:	new submission
Predicate Devices:	VersaCut + Morcellator (K133272) MORCE SCOPE SET 8970 (K041610)

Performance Standards:

There are no mandatory performance standards for this device.

Description of the device:

The MultiCut Solo consists of a special endoscopic handpiece in which a blade is inserted which mechanically shreds the tissue. The blade is driven by a dc motor, which is integrated in the handpiece. The motor itself is driven by a motor driver PCB. The blade can rotate at different speeds and thereby change the direction of rotation periodically (so called oscillation). The morcellator handpiece is also connected by an aspiration tube set to a peristaltic aspiration pump. By this pump the crushed tissue can be transported through a hollow channel in the handpiece to a waste container.

Other characteristics:
The device includes a controlling software.
The device has patient contacting material made of stainless steel which has short term contact (limited contact) with body tissue (External Communicating Device).
The patient contacting components are supplied non-sterile and are intended to be cleaned, disinfected and steam sterilized before the first use and after any following re-use.
The device is intended to solely be used in healthcare facility/hospital environment.

Indications for Use

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.

Nonclinical Performance Data:

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

- EN 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 62304: Medical Device Software - Software life cycle processes
- ISO 14971: Medical devices - Applications of risk management to medical devices
- IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- Comparative bench testing has been performed to show the performance equivalence of the subject device to its predicate

Biocompatibility testing was also conducted for the MultiCut Blades in accordance with:

- EN/ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-18: Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Software verification and validation testing was conducted, and documentation is provided in this submission, as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".
The MultiCut Solo System passed all of the required testing and is in compliance with all applicable sections of the above-mentioned performance standards.

Summary of the technological characteristics of the new device in comparison to the predicate

	Primary Predicate Device	**Secondary Predicate Device**	**Subject Device**
Model Name	VersaCut + Morcellator	MORCE SCOPE SET 8970	MultiCut Solo
Manufacturer	Lumenis LTD	RICHARD WOLF MEDICAL INSTRUMENTS CORP.	Asclepion Laser Technologies GmbH
510(k)	K133272	K041610	-
Principal of Operation	Morcellation through the cutting effect of the cutting window, produced by the relative movement of the internal tube and the external tube.	Morcellation through the cutting effect of the cutting window, produced by the relative movement of the internal tube and the external tube.	Morcellation through the cutting effect of the cutting window, produced by the relative movement of the internal tube and the external tube.
Intended Use	The VersaCut + Tissue Morcellator is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparascopic, percutaneous and open surgical procedures whenever access to the surgical site is limited.	Morce Scope Set 8970, in conjunction with a morcellation probe, and with its sheaths and obturators, is used in the cutting (morcellation) and continuous removal of large tissue masses. In combination with the corresponding auxiliary instruments it can be used as a nephroscope in the disintegration and removal/aspiration of kidney and bladder stones and the removal of tumors via percutaneous (kidney) or transurethral (bladder) passages, in conjunction with intracorporeal 5-4ithotripters e.g. operated pneumatically, by ultrasound, electrohydraulically or by laser, under endoscopic control. The POWER CONTROL 2303 in conjunction with POWER STICK M4 serves to drive WOLF morcellators for the continuous removal of ablated tissue in endoscopic operations.The SUCTION	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.

	Primary Predicate Device	Secondary Predicate Device	Subject Device
		PUMP is used for aspirating irrigation fluid in conjunction with a resectoscope or a morcellator following laser TURP.	
Speed Regulation	Possible from the vacuum generator	Possible from the vacuum generator	Possible from the vacuum generator
External Tube Dimension	39.5 cm length 0.47 cm external diameter	35 or 38 cm length 0.475 cm external diameter	35.0 or 40.0 cm length 0.47 cm (15 Fr) external diameter
Material in Contact with Tissue	Stainless steel	Stainless steel	Stainless steel
Power Supply	AC Power Supplied	AC Power Supplied	AC Power Supplied
Rotation Speed	Up to 600 rpm	Up to 6000 rpm	Up to 3000 rpm
Aspiration	Max 1.65 l/min	Max. 1,3 l/min	Max 1.1 l/min
Electrical Requirements	100-240 V , 50/60 Hz , max 200 VA	100-240 V , 50/60 Hz , max 120 VA	~100-240 V, 50/60 Hz, max. 90 VA
Suction Pump	Part of System Console	Part of System Console	Part of System Console
Supplied Sterile	NO	NO	NO
Re-Usable	YES	Provided Single or PluriUse	YES

Comparison with predicate device:

The subject and predicate devices have similar intended use and the same fundamental principles of surgical cutting and aspiration of dissected tissue. Any minor difference does not raise concern about safety and effectiveness.

Conclusions

The non-clinical performance testing conducted supports that the device can be used safely and effectively. The differences in the indications for use and technological characteristics 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.