November 6, 2024

Asclepion Laser Technologies GmbH
Tom Gruender
RA Manager
Bruesseler Strasse 10
Jena, 07745
GERMANY

Re: K240831
Trade/Device Name: MultiCut Solo
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ

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.

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,

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
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)*

K240831

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

Applicant / Manufacturer Name and Address:	Asclepion Laser Technologies GmbH Bruesseler Strasse, 10 07745 Jena Germany
510(k) Contact Person:	Mr. Tom Gruender Regulatory Affairs Manager Tel.: 0049 3641 7700 201 E-Mail: tom.gruender@asclepion.com
Date Prepared:	02/28/2024
Common name:	Soft Tissue Morcellator and Accessories
Device name:	MultiCut Solo
Regulatory Class:	Class II
Classification Name:	Endoscope and Accessories
Regulation Number:	21 CER 876.1500
Product Code:	GCJ
Basis for Submission:	modifications to the already cleared device
Predicate Devices:	MultiCut Solo (K213597)

Performance Standards:

There are no mandatory performance standards for this device.

Description of the device:

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.
The device is available with either sterile single use blades and non-sterile reusable blades.

Description of the modifications:
Compared to the unmodified device, the subject device includes single use blades in addition to the reusable ones.
Single use blades are supplied sterile, following Ethylene Oxide sterilization process.
The subject device has the same intended use of the unmodified device. Moreover the 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 the following testing:

- Sterile barrier validation
- Sterilization validation
- Measurement of sterilant residuals that remain on the device

Intended Use/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

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.

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.

Summary

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