April 13, 2022

Asclepion Laser Technologies GmbH
Dania Paolo
Regulatory Affairs Manager
Bruesseler Strasse 10
Jena, Thuringia 07747
Germany

Re: K210634
Trade/Device Name: MCL 31 Dermablate System
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: February 25, 2021
Received: March 3, 2021

Dear Dania Paolo:

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,

Purva Pandya, D.Eng.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210634

Device Name
MCL 31 Dermablate System

Indications for Use *(Describe)*

The MCL 31 Dermablate System with its accessories is indicated for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry, and Ophthalmology (skin around the eyes).

The MCL 31 Dermablate System, when used with its micro beam handpieces, is intended for use in Dermatological procedures and Skin resurfacing procedures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K210634
510(k) Summary

Submitter: ASCLEPION LASER TECHNOLOGIES GmbH
Bruesseler Str. 10
07747 Jena, Germany

Contact Person: Tom Gruender
Regulatory Affairs Manager
ASCLEPION LASER TECHNOLOGIES GmbH

Phone: +49 3641 77 00 201
Fax: +49 3641 77 00 302
e-mail: tom.gruender@asclepion.com

Preparation Date: April 12, 2022

Device Trade Name: MCL 31 Dermablate System

Common Name: Er:YAG laser

Classification Name: Powered Laser Surgical Instrument

Regulation Number: 21 CFR 878.4810

Regulatory Class: Class II

Product Code: GEX

Submission Type: Traditional 510(K)

Legally Marketed Predicate Devices:

- MCL 31 Dermablate (K150140) – Asclepion Laser Technologies
- MicroSpot (K152153) – Asclepion Laser Technologies

Device Description:
The MCL 31 Dermablate System is a pulsed Er:YAG laser emitting a wavelength of 2940 nm. The system comprises a main console unit, detachable handpieces, and a footswitch. The MCL 31 Dermablate System can be operated with micro beam and non-micro beam handpieces. The system incorporates a suction unit for the safe removal of laser plume. The laser is fired with a foot-operated switch (footswitch).

Intended Use/Indications for Use:
The MCL 31 Dermablate System with its accessories is indicated for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry, and Ophthalmology (skin around the eyes).

The MCL 31 Dermablate System, when used with its micro beam handpieces, is intended for use in Dermatological procedures and Skin resurfacing procedures.

Summary of Technical Characteristics:
The MCL 31 Dermablate System that is the subject of this submission has identical technical characteristics as the previously cleared MCL 31 Dermablate System (K150140) and its MicroSpot handpiece (K152153).

The MY JULIET handpiece has similar technical characteristics, design, and functional features as the MicroSpot handpiece (K152153) for the MCL 31 Dermablate System, except for the differences shown

in the table below. The minor differences in technical characteristics do not raise any new or different questions of safety or effectiveness.

Comparison with Predicate Devices:
The MCL 31 Dermablate System is substantially equivalent to the predicates with the same intended use and similar indications for use and technological characteristics including wavelength, spot size, and energy delivery.

Specification	This Application	Predicate Devices	
Trade/Device Name	**MCL 31 Dermablate**	MCL 31 Dermablate	MicroSpot Handpiece
Submitter	Asclepion Laser Technologies GmbH	Asclepion Laser Technologies GmbH	Asclepion Laser Technologies GmbH
510(k) number	K210634	K150140	K152153
Indications for use	The MCL 31 Dermablate System with its accessories is indicated for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry, and Ophthalmology (skin around the eyes). The MCL 31 Dermablate System, when used with its micro beam handpieces, is intended for use in Dermatological procedures and Skin resurfacing procedures.	Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes)	The MicroSpot Handpiece is intended for Dermatological procedures and Skin resurfacing procedures.
Laser medium	Er:YAG	Er:YAG	Er:YAG
Wavelength	2940 nm	2940 nm	2940 nm
Fluence, max.	VarioTEAM Handpiece: 250 J/cm^2 MicroSpot Handpiece: 10 J/cm^2 (Up to 150 J/cm^2 with stacking pulses) MY JULIET Handpiece: 5 J/cm^2 (Up to 35 J/cm^2 with stacking pulses)	VarioTEAM Handpiece: 250 J/cm^2	MicroSpot Handpiece: 10 J/cm^2 (Up to 150 J/cm^2 with stacking pulses)
Energy, max	2.5 J 12 mJ/microbeam (for MicroSpot Handpiece) 7 mJ/microbeam (for My Juliet)	2.5 J	12 mJ/microbeam
Pulse Duration	100 – 1000 µs	100 – 1000 µs	100 – 1000 µs
Repetition rate, max	20 Hz	20 Hz	20 Hz
Treatment area / Spot size	VarioTEAM Handpiece: 1 – 12 mm MicroSpot Handpiece: 350 µm - 600 µm spot, MY JULIET Handpiece: 425 µm & 600 µm spot,	VarioTEAM Handpiece: 1 – 12 mm	MicroSpot Handpiece: 350 µm - 600 µm spot,
WLAN module	No	Yes	Yes
Delivery system	Articulated Arm	Articulated Arm	Articulated Arm

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 60601-2-22: Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- EN/IEC 60825-1: Safety of laser products - Part 1: Equipment classification, and requirements
- IEC 62304: Medical Device Software - Software life cycle processes
- ISO 14971: Medical devices - Applications of risk management to medical devices

Biocompatibility testing was also conducted for the MY JULIET handpiece 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 10993-10: Biological evaluation of medical devices - Part 10 Tests for irritation and skin sensitization
- ISO 10993-23: Biological evaluation of medical devices - Part 23 Tests for irritation.

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*".

Biocompatibility: The biocompatibility of MCL 31 Dermablate System and compatible handpieces with the extended indications is established based on the legally marketed predicate devices. For the MY JULIET handpiece testing was conducted regarding Cytotoxicity, Sensitivity and Irritation.

The MCL 31 Dermablate System passed all required testing and is in compliance with all applicable sections of the above-mentioned performance standards.

Conclusion:
The MCL 31 Dermablate System has the same intended use and similar indications for use, technological characteristics, and principles of operation as the predicate devices. The minor differences in indications for use and technical characteristics do not raise different questions of safety or effectiveness. Thus, the MCL 31 Dermablate System is substantially equivalent to the predicate devices.