April 23, 2024

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

Re: K240816
Trade/Device Name: MeDioStar
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: March 21, 2024
Received: March 25, 2024

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,

Tanisha L. Hithe -S
Digitally signed by Tanisha L. Hithe -S
Date: 2024.04.23 13:55:03 -04'00'

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

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.

510(k) Number *(if known)*
K240816

Device Name
MeDioStar

Indications for Use *(Describe)*
The MeDioStar laser system is intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology.

The MeDioStar laser system is intended for the treatment of benign vascular lesions.

The MeDioStar laser system is intended for the treatment of benign pigmented lesions.

The MeDioStar laser system is intended for hair removal, permanent hair reduction defined as reduced hair growth with or without maintenance when measured at 6, 9 and 12 months..

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.

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510(k) Summary for K240816

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:	20/02/2024
Trade Name:	MeDioStar
Common Name:	MeDioStar Diode Laser device
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Main Predicate Device	MeDioStar (K192483), Asclepion Laser Technologies GmbH
Reference Device	LightSheer Infinity (K170179), Lumenis Ltd.

Performance Standards:
There are no mandatory performance standards for this device.

Description of the device:

The modified MeDioStar is a pulsed diode laser emitting a wavelength of 755 - 1060 nm that is operated with a handpiece in contact with the skin. The system comprises a main console unit, a handpiece and is triggered by means of a footswitch. There are several handpieces, the user can choose from. Moreover, a specific software controls the device functions and allows the user selections through the touchscreen display.

Description of the modifications:
The laser is a modification to previously cleared MeDioStar due to some technical modifications concerning the wavelength range.

The subject device has the same technological characteristics (material, components, energy source) as the predicate device except for the differences shown in the table below:

	Main Predicate Device	**Reference Predicate Device**	**Subject device**
	MeDioStar	**LightSheer Infinity**	**MeDioStar**
510k number	**K192483**	**K170179**	**-**
Wavelength	755 – 950 nm	805 – 1060 nm	755 – 1060 nm

The modified device has the same intended use of the unmodified device MeDioStar. Moreover, 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 performance testing and software verifications and validation according to the relevant standards.

Indications for Use:
The MeDioStar laser system is intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology.

The MeDioStar laser system is intended for the treatment of benign vascular lesions.

The MeDioStar laser system is intended for the treatment of benign pigmented lesions.

The MeDioStar laser system is intended for hair removal, permanent hair reduction defined as reduced hair growth with or without maintenance when measured at 6, 9 and 12 months..

Technological Characteristics Comparison

	Main Predicate Device	**Reference Predicate Device**	**Subject device**
	MeDioStar	**LightSheer Infinity**	**MeDioStar**
510k number	**K192483**	**K170179**	**-**
Device Type	Diode Laser	Diode Laser	Diode Laser
Wavelength	755 – 950 nm	805 – 1060 nm	755 – 1060 nm
Pulse Duration	Up to 400 ms	Up to 400 ms	Up to 400 ms
Repetition Rate	Up to 20 Hz	Up to 3 Hz	Up to 20 Hz
Max fluence	210 J/cm²	80 J/cm²	210 J/cm²

Handpiece Port	Double	Single	Double

Non clinical Performance Data:

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

- ISO 60601-1: Medical electrical equipment – Part 1: General requirements for safety and essential performance
- ISO 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 62304: Medical Device Software – Software life cycle processes
- IEC 62366-1: Medical devices – Application of usability engineering to medical devices
- IEC 60601-2-22: Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- ISO 14971: Medical devices – Application of risk management to medical devices
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

MeDioStar passed all the required testing and is in compliance will all applicable sections of the abovementioned performance standards.

Biocompatibility:

The biocompatibility of MeDioStar is established based on the predicate devices.

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.

Conclusions

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.