October 13, 2020

Asclepion Laser Technologies Gmbh
Dania Di Pietro Paolo
Executive Director
Busseler Str. 10
Jena, Thuringia 07747
Germany

Re: K192483
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

Dear Dania Di Pietro Paolo:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 13, 2020. Specifically, FDA is updating the SE Letter to address the error in the company name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Purva Pandya, OHT4: Office of Surgical and Infection Control Devices, 240-402-9979, purva.pandya@fda.hhs.gov.

Sincerely,

Purva U. Pandya -S

Purva Pandya
Acting Assistant Director
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Aslepion Laser Technologies GmbH
Dania Di Pietro Paolo
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Busseler Str. 10
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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: February 24, 2020
Received: February 27, 2020

Dear Dania Di Pietro 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,

Jessica Mavadia-shukla -S

Jessica Mavadia-Shukla, Ph.D.
Acting 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)*
K192483

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.

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Special 510(k) SUMMARY K192483

MeDioStar

This Special 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH MeDioStar is submitted in accordance with the requirements of 21 CFR 907.92 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. Dania Di Pietro Paolo, Ph.D Regulatory Affairs Manager
Phone:	+49 3641 77 00 213
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Preparation Date:	November 8th, 2019
Trade Name:	MeDioStar
Common Name:	MeDioStar Diode Laser device

Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology 79-GEX 21 CFR 878.4810 Regulatory Class: Class II Product Code: GEX
Main predicate device:	The MeDioStar NeXT Family (K143519)
Reference predicate devices	Primelase Excellence (K191321) LightSheer Infinity /Duet/ and Desire (K170179)
Device Description:	The MeDioStar is a pulsed diode laser emitting a wavelength of 750 - 950 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 NeXT Family K143519 due to some technical modifications.
Intended 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.

Description of the modifications:

This Special 510(k) of MeDioStar is submitted due to Device Modifications of the already cleared device The MeDioStar NeXT Family (K143519) due to some technical modifications. 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.

	The MeDioStar NeXT Family	**LightSheer Infinity /Duet/ and Desire**	**Primelase Excellence**	**Subject Device**
software	-	-	-	GUI Design changed
Handpiece Port	Single	Double	Single	Double
Repetition Rate	4-12 Hz	Up to 3 Hz	Up to 10 Hz	Up to 20 Hz
Handpieces	-	-	-	Slightly changes in the dimension and max Fluence per handpiece
USB drive for patient data transfer	Yes	No	-	No

The modified device has the same intended use of the unmodified device MeDioStar NeXT Family (K143519). Moreover, the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

The functionality of MeDioStar with two handpiece ports was tested successfully by means of software verification and validation. Furthermore, the MeDioStar laser with two handpiece ports is substantially equivalent to the Lumenis LightSheer diode laser K170179 with similar parameter and the same Indications for use.

Compared to the predicate device MeDioStar NeXt Family, the maximum adjustable fluence in case of hair reduction changed slightly: this is due to the fact that the high power (HP) hand piece is not included in this submission.

Briefly, 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.

A comparison of the technical characteristics of the subject device and its predicates follows:

	Subject device	**Main predicate device**	**Reference predicate device**	**Reference predicate device**
model name	MeDioStar	MeDioStar NeXT Family	Primelase Excellence	LightSheer Infinity /Duet/ and Desire
manufacturer	Asclepion Laser Technologies GmbH	Asclepion Laser Technologies GmbH	High Technology Products SLU	Lumenis Ltd
510(k)	(K192483)	K143519	K191321	K170179
Laser Source	Diode Laser	Diode Laser	Diode Laser	Diode Laser
Wavelength range	755-950	755-950	805-1060	805-1060
Pulse duration	Up to 400 ms	Up to 400 ms	Up to 400 ms	Up to 400 ms
Max. Fluence (J/cm²)	210	210	43	100
Max. Fluence (J/cm²) Hair reduction	60	90 (HP handpiece), otherwise 60	43	100
Repetition Rate	Up to 20 Hz	4 – 12 Hz	Up to 10 Hz	Up to 3 Hz
Intended Use	Intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology. Intended for the treatment of benign vascular lesions. Intended for hair removal, permanent hair reduction and the treatment of benign pigmented lesions.	Intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology. Intended for the treatment of vascular lesions. Intended for hair removal, permanent hair reduction and the treatment of pigmented lesions.	Intended for hair removal and permanent hair reduction	Intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology. Intended for the treatment of benign vascular lesions. Intended for hair removal, permanent hair reduction and the treatment of benign pigmented lesions.
Handpiece Port	Double	Single	Single	Double

Comparison to: The MeDioStar laser system is substantially equivalent to the MeDioStar NeXT Family K143519 with the same principles of operation, with similar parameter and the same indications for use.
The fundamental scientific technology of the device is unchanged from the legally marketed predicate.
The MeDioStar laser with two handpiece ports is substantially equivalent to the Lumenis LightSheer diode laser K170179 with similar parameter and the same Indications for use.

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 62304:2006+A1:2015 Medical Device Software – Software life cycle processes
- IEC 62366-1 Medical devices – Application of usability engineering to medical devices
- IEC 60601-2-22 Ed.3.1 Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- ISO 14971 2nd Ed. 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 above-mentioned performance standards.

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

Clinical Performance Data: None

Comparison with predicate device

The subject device and predicate device MeDioStar NeXT Family have the same intended use and the same fundamental scientific technology, based on diode laser sources.

Summary

The device MeDioStar is substantially equivalent to its identified predicate device MeDioStar NeXT Family (K143519).