DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 10, 2015

Asclepion Laser Technologies GmbH
Antje Katzer
Regulatory Affairs Manager
Brüsseler Straße 10
07747 Jena, Thuringia
Germany

Re: K143519
Trade/Device Name: MeDioStar NeXT Family
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 5, 2015
Received: February 11, 2015

Dear Ms. Antje Katzer:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143519

Device Name

MeDioStar NeXT Family

Indications for Use *(Describe)*

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

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

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

The MeDioStar NeXT Family 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)

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Asclepion Laser Technologies GmbH • Brüsseler Str. 10 • 07747 Jena • Germany

Special 510(k) SUMMARY

MeDioStar NeXT Family

This Special 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH MeDioStar NeXT Family 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. Antje Katzer Product Management and International Regulatory Affairs
Phone: Fax: e-mail:	+49 3641 77 00 309 +49 3641 77 00 302 antje.katzer@asclepion.com
Preparation Date:	March 5, 2015
Device Name:	MeDioStar NeXT Family
Common Name:	Diode Laser

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
Equivalent Devices:	MeDioStar NeXT K111851 Alma Lasers 755 nm Diode Module K140009
Device Description:	The MeDioStar NeXT and the MeDioStar NeXT^{PRO} (The MeDioStar NeXT Family) are pulsed diode lasers emitting a wavelength of 755 - 950 nm, that are operated with a handpiece in contact with the skin. The lasers are a modification to previously cleared MeDioStar NeXT K111851. All systems comprise a main console unit, a handpiece and are triggered by means of a footswitch. There are several handpieces, the user can chose from.
Intended Use:	The MeDioStar NeXT Family laser system is intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology. The MeDioStar NeXT Family laser system is intended for the treatment of benign vascular lesions. The MeDioStar NeXT Family laser system is intended for the treatment of benign pigmented lesions. The MeDioStar NeXT Family 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.

Summary of Technical Characteristics

	Un-Modified Predicate Device	**Un-Modified Predicate Device**	**Proposed Modified Device**	**Proposed Modified Device**
	MedioStar NeXT	**Alma Lasers 755 nm Diode Module**	**The MeDioStar NeXT Family**	
			MeDioStar NeXT^{PRO}	**MeDioStar NeXT**
	K111851	**K140009**		
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 vascular lesions. Intended for hair removal, permanent hair reduction and the treatment of pigmented lesions.	Permanent reduction in hair regrowth. Treatment of benign vascular and pigmented lesions. Indicated for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin. Permanent reduction in hair regrowth is defined as long term, stable reduction in the numbers of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime.	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 the treatment of benign pigmented lesions. Intended for hair removal, permanent hair reduction defined as reduced hair growth with or without maintenance when measured at 6, 9 and 12 months.	
Device Type	Diode Laser	Diode Laser	Diode Laser	Diode Laser
Wavelength	800 - 950 nm	755 nm	755 – 950 nm	755 – 950 nm
Pulse Duration	Up to 400 ms	Up to 200 ms	Up to 400 ms	Up to 400 ms
Repetition Rate	4 - 12 Hz	0,5 – 10 Hz	4 – 12 Hz	4 – 12 Hz
Spot Sizes (Handpieces)	13 x 10 mm² (ST) 4 x 3 mm² (VAS) 8 x 6 mm² (HP)	150 mm²	13 x 10 mm² (ST) 4 x 3 mm² (VAS) 8 x 6 mm² (HP) 13 x 10 mm² (ALX) 30 x 10 mm² (XL+XLS) 38 x 24 mm² (XL+XLL)	13 x 10 mm² (ST) 4 x 3 mm² (VAS) 8 x 6 mm² (HP) 13 x 10 mm² (ALX)
Max. Fluence (Handpieces)	44 J/cm² (ST) 90 J/cm² (HP) 210 J/cm² (VAS)	120 J/cm²	44 J/cm² (ST) 90 J/cm² (HP) 210 J/cm² (VAS) 35 J/cm² (ALX) 60 J/cm² (XL+XLS) 20 J/cm² (XL+XLL)	44 J/cm² (ST) 90 J/cm² (HP) 210 J/cm² (VAS) 35 J/cm² (ALX)

Comparison to:	The MeDioStar NeXT Family laser system is substantially equivalent to the MeDioStar NeXT K111851 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 NeXT Family laser with handpiece ALX (755 nm) system is substantially equivalent to the Alma Lasers 755 nm Diode Module K140009 with similar parameter and the same Indications for use.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Conclusion:	The MeDioStar NeXT Family laser system is another safe and effective device for the treatment of benign vascular lesions, for hair removal, permanent hair reduction and the treatment of benign pigmented lesions.