K 111851 (1)

510(k) SUMMARY
ASCLEPION LASER TECHNOLOGIES GmbH
MeDioStar NeXT

JUL - 8 2011

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH MeDioStar NeXT 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
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Preparation Date:	June 24th , 2011
Device Name:	MeDioStar NeXT
Common Name:	MeDioStar NeXT
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology 79-GEX 21 CFR 878.4810
Equivalent Devices:	LightSheer Duet K053628 MeDioStar XT K050900
Device Description:	The MeDioStar NeXT is a pulsed diode laser emitting a wavelength of 800 - 950 nm, that is operated with a handpiece in contact with the skin.

K111851 ②

Intended Use:	The MeDioStar NeXT laser system is intended for surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery and dermatology. The MeDioStar NeXT laser system is intended for the treatment of vascular lesions. The MeDioStar NeXT laser system is intended for hair removal, permanent hair reduction and the treatment of pigmented lesions.
Comparison to:	The MeDioStar NeXT is substantially equivalent to the LightSheer Duet Laser System K053628 with the same principles of operation, with similar parameters and the with the same indications for use. The MeDioStar NeXT is substantially equivalent to the MeDioStar XT Laser System K050900 with similar parameters and with two identical Indications for use.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Conclusion:	The MeDioStar NeXT is another safe and effective device for the treatment of vascular lesions, for hair removal, permanent hair reduction and the treatment of pigmented lesions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Asclepion Laser Technologies GmbH
% Mrs. Antje Katzer
Program Management and
International Regulatory Affairs
Brusseler Str. 10
Jena 07747, Germany

JUL - 8 2011

Re: K111851
Trade/Device Name: MeDioStar NeXT
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: June 24, 2011
Received: June 29, 2011

Dear Mrs. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K111851

Device Name: MeDioStar NeXT

Indications for Use:

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

The MeDioStar NeXT laser system is intended for hair removal, permanent hair reduction and the treatment of pigmented lesions.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111851

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)