DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Asclepion Laser Technologies GmbH
Mrs. Antje Katzer
Product Management and International Regulatory Affairs
Bruesseler Str.10, Jena, Thuringia 07747
Germany

December 11, 2015

Re: K152153
Trade/Device Name: MicroSpot Handpiece
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: November 13, 2015
Received: November 13, 2015

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 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,

Joshua C. Nipper -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)*

K152153

Device Name

MicroSpot Handpiece

Indications for Use *(Describe)*

The MicroSpot Handpiece is intended for 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.

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

Traditional 510(k) SUMMARY

MicroSpot Handpiece

This Traditional 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH MicroSpot Handpiece 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.

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Preparation Date:	December 10, 2015
Device Name:	MicroSpot Handpiece
Common Name:	Microbeam Handpiece for Er:YAG 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:	K081541 K101306 K132806	Dermablate Effect (Asclepion Laser Technologies) Fotona Dynamis Er:YAG Laser System (Fotona) Fotona FS-01 Laser Handpiece (Fotona)
Device Description:	The MicroSpot Handpiece is a handpiece with microbeam output to be used with the previously cleared MCL 31 Dermablate (K150140). The MCL 31 Dermablate is a pulsed Er:YAG laser emitting a wavelength of 2940 nm. The system comprises a main console unit, a handpiece and is triggered by means of a footswitch. The MCL 31 can be operated with a handpiece of larger spotsize or with a microbeam handpiece. The system incorporates a suction unit for the safe removal of laser plume.	
Intended Use:	The MicroSpot handpiece is intended for Dermatological procedures and Skin resurfacing procedures.	

Summary of Technical Characteristics

	Proposed Modified Device	**Un-Modified Predicate Device**	**Un-Modified Predicate Device**
Name Manufacturer 510(k)	MCL 31 Dermablate with MicroSpot Zoom Handpiece Asclepion Laser Technologies	Dermablate Effect with MicroSpot - Zoom handpiece Asclepion Laser Technologies K081541	Dynamis Er:YAG Laser System Family with FS 01-Handpiece Fotona K101306 / K132806
Intended Use (Microbeam handpiece)	Dermatological procedures. Skin resurfacing procedures.	Dermatological procedures. Skin resurfacing procedures.	Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece.
Laser medium wavelength	Er:YAG 2940 nm	Er:YAG 2940 nm	Er :YAG 2940 nm
Energy, max.	2,5 J	1,5 J	3,0 J
Power, max.	20 W	12 W	20 W
Frequency, max.	20 Hz	20 Hz	50 Hz
Fluence, max.	10 J/cm² Up to 150 J/cm² with stacking pulses	18 J/cm² Up to 162 J/cm² with stacking pulses	Up to 800 J/cm² with stacking pulses
Max. Energy per Microbeam	12 mJ	8 mJ	160 mJ
Pulse Duration	0,1 – 1,0 ms	< 1 ms	0,1 – 1,5 ms
Pulse repetition rate	Up to 20 Hz	Up to 20 Hz	Up to 50 Hz
Spot size of microbeams	350 and 600 µm	250 µm	250 µm
Creation of microbeams	By microlens array	By microlens array	By microlens array
Treatment zones	13 x 13 mm	13 x 13 mm 9 x 9 mm 7 x 7 mm	13 x 13 mm
Coverage of skin	10 and 25 %	5 – 17 %	5 – 60 %

Comparison to: The MicroSpot Handpiece of the MCL 31 Dermablate laser system is substantially equivalent to the MicroSpot Handpiece of the Dermablate Effect K081541 and the Fotona FS-01 Laser Handpiece K132806 of the Fotona Dynamis Er:YAG laser K101306 with the same principles of operation, with similar parameters and with similar indications for use. The fundamental scientific technology of the device is unchanged from the legally marketed predicates.

Nonclinical Performance Data: The MicroSpot Handpiece is designed and tested according to following standards:

ISO 14971:2009
IEC 60601-1:2005
IEC 60601-1-2:2007
IEC 60601-1-6:2010
IEC 60601-2-22:2007
IEC 60825-1:2007
IEC 62304:2006

Laboratory testing was conducted to validate and verify that the MicroSpot Handpiece met all design specifications and was substantially equivalent to the predicate devices.
The size of the single microspots was evaluated as well as the laser pulse duration, the energy release of the laser and the energy in a duration test.
The results of those testings were used to select the desired parameters with the MicroSpot handpiece.

Animal Performance Data: Histological data was submitted to support safety and effectiveness of the microbeam mode.
The device was used in vivo on pig skin with low, medium and high energies, and with different pulse durations and densities. The five possible settings of the handpiece were applied to nine pigs. Three received 20 J/cm², three received 40 J/cm² and three received 60 J/cm². The histological samples have been collected at day 0, 3 and 14.
The biopsied areas show the depth and width of ablation as well as the thermal damage zones and demonstrate the healing response over time.

Conclusion: The MicroSpot Handpiece is another safe and effective device for Dermatological and Skin resurfacing procedures.