510(k) SUMMARY
ASCLEPION LASER TECHNOLOGIES GmbH
TattooStar Effect Combo

JUL 17 2014
K131757

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH TattooStar Effect Combo is submitted in accordance with the requirements of 21 CFR 807.92 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 Manager and International Regulatory Affairs Manager
Phone: Fax: e-mail:	+49 3641 77 00 309 +49 3641 77 00 302 antje.katzer@asclepion.com
Preparation Date:	July 15, 2014
Device Name:	TattooStar Effect Combo
Common Name:	q-switch laser
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology 79-GEX 21 CFR 878.4810
Equivalent Devices:	TattooStar Effect Y K112669 TattooStar R K060787
Device Description:	The TattooStar Effect Combo is a combination of a Nd:YAG laser and a Ruby laser. Both lasers are pulsed q-switched lasers, the Nd:YAG can optionally emit millisecond pulses in the Free-running mode. The Nd:YAG laser emits wavelengths of 1064nm and 532nm. The beam can be converted to 585nm by means of an optional dye handpiece. The Ruby laser emits 694 nm radiation.

Intended Use: The TattooStar Effect Combo is indicated for incision, excision, ablation and vaporization of soft tissue in general dermatology and the removal of tattoos, pigmented lesions, vascular lesions and unwanted hair and skin resurfacing procedures.

	Proposed Modified Device	**Un-Modified Predicate Device**
Name	TattooStar Effect Combo Modul: R (Ruby laser)	TattooStar R K060787
Indications	Incision, excision, vaporization and ablation of soft tissue, the removal of tattoos and benign pigmented lesions	Cutting, vaporization and ablation of soft tissue, the removal of tattoos and of benign pigmented lesions
	There are the same treatment recommendations for both systems: 694nm: Removal of pigmented lesions: 3 J/cm², 4-5.5 mm, 0.5-2 Hz, 40 ns Removal of black, blue and green tattoo: 2-3 J/cm², 4-5.5 mm, 0.5-2 Hz, 40 ns	
Device Type	Ruby	Ruby
Delivery	Articulated mirror arm	Articulated mirror arm
Wavelength	694 nm	694 nm
Max. Energy per Pulse	1,15 J	1,2 J
Max. Fluence on skin	25 J/cm^2	20 J/cm²
Pulse Duration q-switch	40 ns	40 ns
Repetition Rate	Up to 2 Hz	Up to 2 Hz
Spot Sizes	2 – 7 mm	2,5 - 6 mm

	Proposed Modified Device	**Un-Modified Predicate Device**
Name	TattooStar Effect Combo Modul: Y (Nd:YAG laser)	TattooStar Effect Y Modul: Y (Nd:YAG laser) K112669
Indications	Incision, excision, vaporization and ablation of soft tissue, the removal of tattoos, pigmented lesions, vascular lesions and hair and skin resurfacing procedures	Incision, excision, vaporization and ablation of soft tissue, the removal of tattoos, pigmented lesions, vascular lesions and hair and skin resurfacing procedures
	There are the same treatment recommendations for both systems: 1064 nm: Removal of black and blue tattoo color: 3-3.5 J/cm², 2-4 mm, 1-10 Hz, 8 ns Skin resurfacing: 1.5-2.5 J/cm², 5.5 mm, 10 Hz, 0.3 ms 1.5 J/cm², 7 mm, 2-5 Hz, 8 ns 532 nm: Removal of pigmented lesions (including but not limited to lentigo benigna, hyperpigmented burn and boil scar, naevus Ota / Ito, freckles, Becker naevi, Café-au-lait spots): 2-2.5 J/cm², 4 mm, 1-5 Hz, 8 ns Removal of red tattoo color: 2 J/cm², 4 mm, 1-5 Hz, 8 ns 585 nm: Removal of sky blue tattoo color: 2-3 J/cm², 2.5 mm, 1-5 Hz, 8 ns	
Device Type	Nd :YAG	Nd :YAG
Delivery	Articulated mirror arm	Articulated mirror arm
Wavelength	1064 / 532 / 585 nm	1064 / 532 / 585 nm
Max. Energy per Pulse	1064 nm: 0,8 J (q-switch mode) 1064 nm: 1,5 J (free running mode) 532 nm: 0,4 J (q-switch mode) 585 nm: 0,25 J (q-switch mode)	1064 nm: 0,8 J (q-switch mode) 1064 nm: 1,5 J (free running mode) 532 nm: 0,4 J (q-switch mode) 585 nm: 0,25 J (q-switch mode)
Max. Fluence on skin	20 J/cm² (q-switch mode) 37 J/cm² (free running mode)	20 J/cm² (q-switch mode) 37 J/cm² (free running mode)

Pulse Duration q-switch	8 ns (q-switch mode) 300 µs (free running mode)	8 ns (q-switch mode) 300 µs (free running mode)
Repetition Rate	Up to 10 Hz	Up to 10 Hz
Spot Sizes	2 – 7 mm	2 – 7 mm

Comparison to: The TattooStar Effect Combo is substantially equivalent to the TattooStar Effect Y Laser system and to the TattooStar R with the same principles of operation, with the same parameters and with the same indications for use.

Nonclinical Performance Data: None

Clinical Performance Data: None

Conclusion: The TattooStar Effect Combo is another safe and effective device for the incision, excision, ablation and vaporization of soft tissue in general dermatology and the removal of tattoos, pigmented lesions, vascular lesions and unwanted hair and skin resurfacing procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 17, 2014

Asclepion Laser Technologies GmbH
Mr. Antje Katze
Regulatory Affairs Manager
Bruesseler Street 10
Jena, Germany 07747

Re: K131757
Trade/Device Name: TattooStar Effect Combo
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 20, 2014
Received: June 24, 2014

Dear Mr. 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 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. 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,

David Krause -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)*
K131757

Device Name
TattooStar Effect Combo

Indications for Use *(Describe)*
The TattooStar Effect Combo is indicated for incision, excision, ablation and vaporization of soft tissue in general dermatology and the removal of tattoos, pigmented lesions, vascular lesions and skin resurfacing procedures. Depending on the wavelength selected, the indications are as follows:

Wavelength	Indication	Recommended Parameters for the Beginning
1064 nm:	Removal of black and blue tattoo color	3-3.5 J/cm^2 , 2-4 mm, 1-10Hz, 8 ns
	Skin resurfacing	1.5-2.5 J/cm^2, 5.5 mm, 10 Hz, 0.3 ms 1.5 J/cm^2, 7 mm, 2-5 Hz, 8 ns
532 nm:	Removal of pigmented lesions (including but not limited to lentigo benigna, hyperpigmented bum and boil scar, naevus Ota / Ito, freckles, Becker naevi, Cafe-au-lait spots)	2-2.5 J/cm^2 4mm, 1-5Hz, 8 ns
	Removal of red tattoo color	2 J/cm^2, 4mm, 1-5Hz, 8ns
585 nm:	Removal of sky blue tattoo color	2-3 J/cm^2, 2.5mm, 1-5Hz, 8 ns
694nm:	Removal of pigmented lesions	3 J/cm^2, 4-5.5 mm, 0.5-2 Hz, 40 ns
	Removal of black, blue and green tattoo color	2-3 J/cm^2, 4-5.5 mm, 0.5-2 Hz, 40 ns

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.07.17 11:18:23 -04'00'

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