K060787

SEP 27 2006

# 510(k) SUMMARY
# ASCLEPION LASER TECHNOLOGIES GmbH
# TattooStar family

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

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| Applicant: | ASCLEPION LASER TECHNOLOGIES GmbH<br>Am Semmicht 1A<br>07755 Jena, Germany |
| Contact Person: | Mr Reinhard Thieme<br>Quality Assurance and<br>International Regulatory Affairs |
| Phone:<br>Fax:<br>e-mail: | +49 3641 77 00 251<br>+49 3641 77 00 102<br>reinhard.thieme@asclepion.com |
| Preparation Date: | June 18th, 2006 |
| Device Name: | TattooStar R |
| Common Name: | TattooStar R |
| Classification Name: | Instrument, surgical, powered, laser<br>79-GEX<br>21 CFR 878.481 |
| Equivalent Device: | RubyStar |
| Device Description: | The TattooStar R is a q-switched solid state lasers emitting wavelengths of 694 nm (Rubylaser). It consists a laser enclosure and optic delivery system (articulated mirror arm). |
| Intended Use: | The TattooStar R is indicated of cutting, vaporization or ablation of soft tissue. This includes tattoo removal and treatment of benign pigmented lesions. |
| Comparison to: | The TattooStar R is substantially equivalent to the RubyStar, with the same principles of operation, and the same indication for use ,the same wavelength but without a long pulsed mode which is used for hair removal. |

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| Nonclinical Performance Data: | None |
| Clinical Performance Data: | None |
| Conclusion: | The TattooStar R is another safe and effective device for the removal of tattoos and pigmented lesions and for ablation, cutting, vaporization of soft tissue for general dermatology. |
| Additional Information : | None |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Asclepion Laser Technologies GmbH
% Reinhard Thieme
Quality Assurance Manager
Am Semmicht 1A
07755 Jena, Germany

SEP 27 2006

Re: K060787
Trade/Device Name: TattooStar R
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 24, 2006
Received: August 28, 2006

Dear Reinhard Thieme:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060787

Device Name: TattooStar R

Indications for Use:

The TattooStar R is intended for use for cutting, vaporization and ablation of soft tissue and the removal of tattoos and benign pigment lesion.

Some examples of pigment lesions are:

Lentigines, Café-au-lait-blotches, Ephalides, BenignNaevi such as Naevus of Ota, Naevus of Ito, Epidermal Naevi, Congenital Naevi, Beckers Naevi, Blue Nevus, Naevus Spillus and Mongolian Spot.

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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