K113489 1/2

# 510(k) SUMMARY
# ASCLEPION LASER TECHNOLOGIES GmbH
# Orion

JUL 27 2012

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH Orion laser system 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>Bruesseler Str. 10<br>07747 Jena, Germany |
| Contact Person: | Mrs. Antje Katzer<br>Product Management and<br>International Regulatory Affairs |
| Phone:<br>Fax:<br>e-mail: | +49 3641 77 00 309<br>+49 3641 77 00 302<br>antje.katzer@asclepion.com |
| Preparation Date: | November 18th, 2011 |
| Device Name: | Orion |
| Common Name: | Orion |
| Classification Name: | Laser surgical instrument for use in general and plastic surgery and in dermatology<br>79-GEX<br>21 CFR 878.4810 |
| Equivalent Device: | GENTLEray 980 K072262 |
| Device Description: | The Orion laser system is a pulsed and cw diode laser emitting a wavelength of 980 nm, that is intended for ablating, excising and coagulation of intraoral soft tissue using a contact fiber optical delivery system. |

K113489 4/4 2/2

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| Intended Use: | Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue. The device is intended for use in the following procedures: Frenectomy, Frenotomy, Biopsy, Operculectomy, Implant Recovery, Gingivectomy, Gingivoplasty, Gingival Troughing, Crown Lengthening, Hemostasis of Donor Site, Removal of Granulation Tissue, Laser-assisted Flap Surgery, Debridement of Deseased Epithelial Lining, Incisions and Draining of Abscesses, Tissue Retraction for Impressions, Papillectomy, Vestibuloplasty, Excision of Lesions, Leukoplakia, Exposure of Unerupted / Partially Erupted Teeth, Removal of Hyperplastic Tissues, Treatment of Aphthous Ulcers, Sulcular Debridement, Pulpotomy, Pulpotomy as an Adjunct to Root Canal Therapy, and Light Activation of Bleaching Materials. |
| Comparison to: | The Orion is substantially equivalent to the GENTLEray 980 Laser System K072262 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 Orion is as safe and effective as the predicate device and is substantially equivalent. |

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
Product Management & International Regulatory Affairs
Bruesseler Street 10
Jena, Germany 07747

JUL 27 2012

Re: K113489
Trade/Device Name: Orion
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 06, 2012
Received: June 08, 2012

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,

Erin L Keith

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

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number: K113489

Device Name: Orion

Indications for Use:

Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue. The device is intended for use in the following procedures: Frenectomy, Frenotomy, Biopsy, Operculectomy, Implant Recovery, Gingivectomy, Gingivoplasty, Gingival Troughing, Crown Lengthening, Hemostasis of Donor Site, Removal of Granulation Tissue, Laser-assisted Flap Surgery, Debridement of Deseased Epithelial Lining, Incisions and Draining of Abscesses, Tissue Retraction for Impressions, Papillectomy, Vestibuloplasty, Excision of Lesions, Leukoplakia, Exposure of Unerupted / Partially Erupted Teeth, Removal of Hyperplastic Tissues, Treatment of Aphthous Ulcers, Sulcular Debridement, Pulpotomy, Pulpotomy as an Adjunct to Root Canal Therapy, and Light Activation of Bleaching Materials.

Neil R P for mkm

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

510(k) Number K113489

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)