JUN 1 0 2014

510(k) SUMMARY
ASCLEPION LASER TECHNOLOGIES GmbH
K133297
QuadroStarPRO

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH QuadroStarPRO 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
Phone: Fax: e-mail:	+49 3641 77 00 309 +49 3641 77 00 302 antje.katzer@asclepion.com

Preparation Date:	June 10, 2014
Device Name:	QuadroStarPRO
Common Name:	QuadroStarPRO
Classification Name:	Laser surgical instrument for use in general and plastic surgery 79-GEX 21 CFR 878.4810

Equivalent Devices:

K013940	YellowStar	Asclepion-Meditec AG (Assignor of Asclepion Laser Technologies GmbH)
K060457	QuadroStar 532	Asclepion Laser Technologies GmbH

Device Description: The QuadroStarPRO Laser system is a laser Class IV, solid state diode laser, which emits laser radiation with a wavelength of either 577 nm or 532 nm. It`s pulse duration can be varied from millisecond pulses up to continuous operation. The laser power up to 8 Watts is transmitted to the tissue through a transfer fiber and a handpiece, optionally a scanner can be operated.

The laser system consists of:

Laser system including control panel (user interface)
Foot switch
A transfer fiber with handpiece, optional different spacers.

Intended Use: The QuadroStarPRO^{YELLOW} (wavelength: 577nm) is intended for treatment of benign vascular and benign pigmented lesions.

The QuadroStarPRO^{GREEN} (wavelength: 532nm) is intended for vaporisation and photocoagulation of benign vascular and benign pigmented lesions in soft tissue.

Comparison to:

The QuadroStarPRO with 577 nm has identical indications for use as the K013940 YellowStar; the QuadroStarPRO with 532 nm has identical indications for use as the K060457 QuadroStar 532.
Therefore the QuadroStarPRO is found to be substantially equivalent to already marketed and predicate lasers. Both predicates were developed by Asclepion or it`s assignor.
With regard to technology, the QuadroStarPRO is found to be substantially equivalent to K060457 QuadroStar 532, since the basic technology, design and safety features are very similar. With the availability of multi-color diodes it became practicable also to generate wavelengths such as 577 nm by means of modern diode technology, whereas in former times these wavelengths could only be generated with the technology of Copper Bromide or Copper Vapor lasers.
The differences between QuadroStarPRO and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Device	**QuadroStarPRO**	**K013940 YellowStar**	**K060457 QuadroStar 532**
Intended Use	577 nm: intended for treatment of benign vascular and benign pigmented lesions. 532 nm: intended for vaporisation and photocoagulation of benign vascular and benign pigmented lesions in soft tissue.	Intended for treatment of vascular and pigmented lesions.	Intended for vaporization and photocoagulation of vascular and pigmented lesions in soft tissue.
Device Type	Diode pumped solid-state laser	Copper Bromide laser	Diode pumped solid-state laser
Wavelength	532 nm or 577 nm (cannot be combined)	511 nm and 578 nm (single or combined)	532 nm
Principle of operation	Pulsed or cw Optical excitation	Pulsed or Quasi-continuous High voltage excitation	Pulsed or cw Optical excitation
Maximum	8 W (532 nm)	5 W (511 nm)	5 W

Power	5 W (577 nm)	2 W (578 nm) 7 W both/combined	
Energy Range	Up to 1.9 J	Up to 0.4 J	Up to 12.4 J
Device	**QuadroStarPRO**	**K013940** **YellowStar**	**K060457** **QuadroStar 532**
Pulse Duration	1 ms – 95 s and cw	10 – 950 ms and cw	5 ms – 2.5 s and cw
Max. Repetition Rate	20 Hz	16 kHz Quasi-cw	120 Hz
Delivery	Transfer fiber	Transfer fiber	Transfer fiber
Spot diameters	1 mm / optional : 0.5/1.5/2.8 mm Scanner : 1 mm	0.2/0.4/0.6/1.0/1.5 mm	0.5/1.0/1.5 mm
Device Cooling	Internal air cooling	Internal air cooling	Internal air cooling
Power Supply	100 - 240VAC, 50/60Hz	230V 50/60Hz/10 A	115/230V 50/60Hz

Performance Testing: The QuadroStarPRO laser system is tested according to following standards:

ISO 14971:2009
DIN EN 60601-1:2006
DIN EN 60601-1-2:2007
DIN EN 60601-1-6:2007
DIN EN 60601-2-22:1996
DIN EN 60825-1:2007
DIN EN 62304:2006

The device also complies with European Medical Device Directive 93/42/EEC + Amendment 2007/47/EC.

Conclusion: The QuadroStarPRO is substantially equivalent to the cited legally marked predicate devices. The minor differences between QuadroStarPRO and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

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

June 10, 2014

ASCLEPION LASER TECHNOLOGIES GmbH
Ms. Antje Katzer
Product Management and International Regulatory Affairs
Bruesseler Str. 10
07747 Jena, Germany

Re: K133297
Trade/Device Name: QuadroStarPRO
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: May 7, 2014
Received: May 12, 2014

Dear Ms. 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,

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)*
K133297

Device Name

QuadroStarPRO

Indications for Use *(Describe)*

The QuadroStarPROYELLOW (wavelength: 577nm) is intended for treatment of benign vascular and benign pigmented lesions.

The QuadroStarPROGREEN (wavelength: 532nm) is intended for vaporisation and photocoagulation of benign vascular and benign pigmented lesions in soft tissue.

Federal law restricts this device to sale by or on the order of a physician!

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
2014.06.10 15:45:00 -04'00'

FDA

For BSA

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