April 22, 2022

Asclepion Laser Technologies GmbH
Carolin Kuehling
Head of Quality and Regulatory Affairs
Bruesseler Strasse 10
Jena, Thuringia 07747
Germany

Re: K213889
Trade/Device Name: PicoStar
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: December 9, 2021
Received: December 13, 2021

Dear Carolin Kuehling:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya, D.Eng.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213889

Device Name
PicoStar

Indications for Use *(Describe)*
The PicoStar laser system is indicated for the following at the specified wavelength:
532 nm:
Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.
Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-III.

1064 nm:
Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.
Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV.
Only with microspot handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV.
Only with microspot handpiece, indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K213889

510(k) SUMMARY

[As Required by 21 CFR 807.92]

Applicant:	ASCLEPION LASER TECHNOLOGIES GmbH Bruesseler Str. 10 07747 Jena, Germany
510(k) Contact Person:	Mrs. Carolin Kuehling Head of Quality and Regulatory Affairs Phone: +49 3641 77 00 213 Fax:+49 3641 77 00 102 E-mail: carolin.kuehling@asclepion.com
Preparation Date:	December 8th, 2021
Common Name:	Nd:YAG laser
Device Trade Name:	PicoStar
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in Dermatology
Classification	Class II
Regulation Number	21 CFR 878.4810
Product Code	GEX
Submission Type:	Traditional 510(K)

Predicate Device	Discovery Pico Family (K172376)
Device Description:	PicoStar is a solid state laser capable of delivering energy at wavelengths of 1064 nm, or 532 nm at short durations of max 400 picoseconds (ps) and repetition rates up to 10 Hz. The device system is composed of a system console, an articulated arm, and attached delivery handpieces (full spot or microspot). The laser output at each wavelength is delivered to the skin through an articulated arm delivery system terminated by a handpiece. The PicoStar is controlled via a touch screen display housed in the front of the device. The control panel enables the user to select the desired energy density level and repetition rate. Emission is triggered by means of a footswitch.

Indications for Use:

The PicoStar laser system is indicated for the following at the specified wavelength:

532 nm:	Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-III.
1064 nm:	Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. Indicated for benign pigmented lesions removal for Fitzpatrick skin types I-IV. Only with microspot handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV. Only with microspot handpiece, indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V.

Summary of technological characteristics

	Predicate Device		Subject Device	
Model Name	Discovery Pico Family		PicoStar	
Manufacturer	Quanta System SPA		Asclepion Laser Technologies GmbH	
Laser Type	Nd:YAG		Nd:YAG	
Wavelength (nm)	532	1064	532	1064
Delivery System	Articulated arm		Articulated arm	
Max. Pulse duration (ps)	up to 400	up to 450	up to 400	up to 400
Spot size (mm)	up to 12 round up to 9x9 squared		up to 5 round	up to 16 round 7x7 squared
Max Energy (mJ)	300	800	300	800
Pulse Repetition rate (Hz)	Max 10 Hz		Max 10 Hz	
Microspot handpiece	Available		Available	

Non-clinical Performance Data:

The following performance data were applied in support of the substantial equivalence determination:

- ISO 60601-1: Medical electrical equipment – Part 1: General requirements for safety and essential performance
- ISO 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 62304 Medical Device Software – Software life cycle processes
- IEC 60601-2-22 Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- ISO 14971 Medical devices – Application of risk management to medical devices

Software verification and validation testing was conducted and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".
PicoStar passed all the required testing and is in compliance will all applicable sections of the above-mentioned performance standards.

Biocompatibility:
The biocompatibility of PicoStar is established based on the predicate device.

Clinical Performance Data: None

Comparison with predicate device

The PicoStar and the predicate device have the same intended use with similar indications for use.
The PicoStar Laser System presents the same or similar technological characteristics as its predicate devices, including the laser type, wavelengths, device design, pulse width, frequency, spot sizes and system components. Any minor differences do not present any new types of safety or effectiveness questions since the PicoStar parameters are similar to the ones of the predicates. Further, PicoStar performance has been demonstrated in non-clinical performance data, and results confirm the safety and performance of the device. The PicoStar device and its predicate operate with the same mechanism of action based on selective photothermolysis of pigment particles using laser energy. Therefore, the PicoStar has the same intended use and similar indications for use, technological characteristics, and principles of operation as the predicate devices. The PicoStar is substantially equivalent to the predicate device.

Summary

It is demonstrated that the Picostar performs as intended and is substantially equivalent to the predicate device.