Beijing ADSS Development Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

August 23, 2022

Re: K220268
Trade/Device Name: Picosecond Laser System
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: July 12, 2022
Received: July 22, 2022

Dear Boyle Wang:

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,

Neil R.P. Ogden
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)*
K220268

Device Name
Picosecond Laser System

Indications for Use *(Describe)*
The Picosecond Laser System is intended for use in surgical and aesthetic application in the medical dermatology and general and plastic surgery as follows:

1064nm wavelength:
- Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple.
- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.

532nm wavelength:
- Removal of tattoos on Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange.
- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

K220268

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 submitter's Information

Name: Beijing ADSS Development Co., Ltd.
Applicant address: F2,Building 1,Jinyuan Road 36 Daxing Economic Development Zone,102628 Beijing, PEOPLE'S REPUBLIC OF CHINA
Production address: Fuda Road - Tongsheng Road, Southern Area of Industrial Park,Gu'an County, 065599 Langfang City, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
Tel: 86-13051615111
Contact: Song Ying

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
Address: Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: Jul.12th,2022

2.0 Device Information

Trade name: Picosecond Laser System
Common name: Powered Laser Surgical Instrument
Classification name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Model(s): PS10-A, PS10-B
Production code: GEX
Regulation number: 21CFR 878.4810
Classification: Class II
Panel: General & Plastic Surgery

3.0 Predicate Device

Manufacturer: Shanghai Apolo Medical Technology Co., Ltd.
Trade/Device Name: PicoSecond Nd: YAG Laser System
510(k) number: K200116

4.0 Device Description

The Picosecond Laser System consists of a host, a treatment handpiece, a light guide system, a foot switch, power cords and accessories. The host contains a laser, a cooling device, a laser power supply, a control device (including a control device and a LCD) and a protective device. Accessories include a foot switch, a laser protective glasses, power cords, and a water filling device.

The Picosecond Laser System is a multi-wavelength, pulsed laser system. A key feature of the device is its ability to produce two laser wavelengths (i.e., 1064 nm and 532 nm).

5.0 Indication for Use Statement

The Picosecond Laser System is intended for use in surgical and aesthetic application in the medical dermatology and general and plastic surgery as follows:
1064nm wavelength:
- Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple.
- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.

532nm wavelength:
- Removal of tattoos on Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange.
- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.

6.0 Comparison to the Predicate Device

Item	Subject device	Predicate device 1(Primary) K200116
Trade/Device Name	Picosecond Laser System	PicoSecond Nd: YAG Laser System
Manufacturer	Beijing ADSS Development Co., Ltd.	Shanghai Apolo Medical Technology Co., Ltd.
Class &Code	Class II GEX 878.4810	Class II GEX 878.4810
Intended Use/Indication for Use	The Picosecond Laser System is intended for use in surgical and aesthetic application in the medical dermatology and general and plastic surgery as follows: 1064nm wavelength: - Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green,blue and purple. - Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV. 532nm wavelength: - Removal of tattoos on	The PicoSecond Nd: YAG Laser System is intended for use in surgical and aesthetic application in the medical dermatology and general and plastic surgery as follows: 1064nm wavelength: - Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple. - Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV. 532nm wavelength: - Removal of tattoos on Fitzpatrick skin types I-III with

	Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange. - Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.	the following tattoo colors: red, yellow and orange. - Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.
Type of Use	Prescription Use	Prescription Use
Wavelength	1064/532 nm	1064/532 nm
Pulse Duration (Pulse Width)	500ps	300 – 500 ps
Pulse Energy	500mJ(1064nm) 250mJ (532nm)	500mJ(1064nm) 250mJ (532 nm)

Peak Power (Gigawatts)	1.0	Not Publicly Available
Aiming Beam	635nm	Not Publicly Available
Repetition Rate	1~10Hz	Single, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Hz
Spot size	2mm-10mm	Adjustable spot size 2~10mm
Maximum Average Fluence (J/cm²)	1064 nm: 15.5 J/cm² 532 nm: 8 J/cm²	Not Publicly Available
Laser Type	Nd:YAG	Nd:YAG

Activation	foot-switch	foot-switch
Display	LCD Touch screen	LCD Touch screen
Cooling System	Internal water to air heat exchanger	Cooling System
Electrical Power	AC 230V，50Hz	120VAC 10A, 50/60Hz
Beam Delivery System	Articulated Arm with Handpiece	Articulated Arm with Handpiece
System dimension	93cm × 40 cm × 93 cm	97cm H x 48cm W x 97cm D
System Weight (kg)	128 kg	130kg

Analysis:

From the comparison table, the subject device and predicate device have the same Intended use & Indications for Use, and comparable technological parameters.

7.0 Non-Clinical Tests

Non clinical tests were conducted to verify that the subject device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1: 2005+corr.1:2006+Corr.2.2007+A1:2012 Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-22:2012, Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and Requirements
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Software Information: Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”
- Bench Testing: Bench testing was performed to make sure that the device delivers set energy parameters within specifications.

8.0 Clinical Test Conclusion

No clinical study is included in this submission.

9.0 Conclusion

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.