October 1, 2025

Hebei Newangie Technology Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K252447
Trade/Device Name: Picosecond laser device (BMPS4)
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 29, 2025
Received: August 4, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.10.01 15:15:54 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252447

Device Name
Picosecond laser device (BMPS4)

Indications for Use *(Describe)*
The Picosecond Laser device 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.

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510(k) Summary

K252447

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:	Hebei Newangie Technology Co., Ltd.
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Contact:	Mr. Ning Wang

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: Sep.24, 2025

2.0 Device Information

Trade name:	Picosecond laser device
Common name:	Powered Laser Surgical Instrument
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Model:	BMPS4
Production code:	GEX
Regulation number:	21CFR 878.4810
Classification:	Class II
Panel:	General & Plastic Surgery

3.0 Predicate Devices and Reference Device

Predicate Device:

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

Reference Device 1:

Manufacturer: AMI Inc.
Trade/Device Name: PICO LEGEND Nd:YAG Laser System
510(k) number: K233007

Reference Device 2:

Manufacturer: Beijing ADSS Development Co., Ltd.
Trade/Device Name: Picosecond Laser System
510(k) number: K220268

4.0 Device Description

Composition of therapeutic device: main unit, light guide arm, handpiece and foot switch. The main unit includes display screen, laser, power supply, water circulation cooling system and electronic control components.
Accessories include goggles, eye mask,standard hand tools,power cord,fuse tube,funnel component,drain faucet,user manual,remote control interlock connector,drain spout and keys.
The Picosecond Laser Device is a multi-wavelength, pulsed laser system designed for the treatment of benign pigmented lesions and removal of tattoos. A key feature of the device is its ability to produce multiple laser wavelengths (1064 nm and 532 nm).

5.0 Indication for Use Statement

Picosecond laser devices are intended for surgical and cosmetic applications in medical dermatology, general surgery and plastic surgery as follows:
1064nm wavelength：
- Removal of tattoos on all skin types (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple;
- Treatment of benign pigmented lesions in 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 K200116	Reference device 1 K233007	Reference device 2 K220268
Trade/Device Name	Picosecond laser device	PicoSecond Nd: YAG Laser System	PICO LEGEND Nd:YAG Laser System	Picosecond Laser System
Manufacturer	Hebei Newangie Technology Co., Ltd.	Shanghai Apolo Medical Technology Co., Ltd.	AMI Inc.	Beijing ADSS Development Co., Ltd
Class &Code	Class II GEX 878.4810	Class II GEX 878.4810	Class II GEX 878.4810	Class II GEX 878.4810
Intended Use/Indication for Use	Picosecond laser devices are intended for surgical and cosmetic applications in medical dermatology, general surgery and plastic surgery as follows: 1064nm wavelength: - Removal of tattoos on all skin types (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple; - Treatment of benign pigmented lesions in Fitzpatrick skin types I-IV.	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.	The PICO LEGEND Nd:YAG Laser System is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery. -The 1064nm wavelength of the PICO LEGEND Nd:YAG Laser System is indicated for tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick	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.	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.	I-VI). -The 532nm wavelength of the PICO LEGEND Nd:YAG Laser System is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.	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	Prescription Use	Prescription Use	Prescription Use	Prescription Use
Wavelength	1064/532 nm	1064/532 nm	1064/532 nm (Accuracy ±10%)	1064/532 nm
Pulse Duration (Pulse Width)	300 – 500 ps	300 – 500 ps	300 ps - Both Modes	500 ps – Both Modes
Pulse Energy	1064nm mode:100 - 500mJ (Adjustable by 50mJ) 532nm mode: 50 - 250mJ (Adjustable by 25mJ)	500mJ (1064nm) 250mJ (532nm)	1064nm mode: 100 - 500mJ (Adjustable by 25mJ) 532nm mode: 50 - 250mJ (Adjustable by 25mJ)	500mJ (1064nm) 250mJ (532nm)
Aiming Beam	650nm	Not Publicly Available	635nm	635 nm
Repetition Rate	1Hz-10Hz, with a step of 1Hz	Single, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Hz	1Hz-10Hz, (Adjustable by 1Hz)	1Hz-10Hz

Spot size	2mm -10mm, ±20%, with a step of 1mm, - All treatment Modes	Adjustable spot size 2~10mm	2mm - 10mm (Adjustable by 1mm) - All treatment Modes	2mm - 10mm - All treatment Modes
Maximum Average Fluence (J/cm²)	1064 nm: 15.9 J/cm² 532 nm: 8.0 J/cm²	Not Publicly Available	1064 nm: 15.92 J/cm² 532 nm: 7.96 J/cm²	1064 nm: 15.5 J/cm² 532 nm: 8 J/cm²
Laser Type	Nd:YAG	Nd:YAG	Nd:YAG	Nd:YAG
Activation	foot-switch	foot-switch	foot-switch	foot-switch
Display	LCD Touch screen	LCD Touch screen	LCD Touch screen	LCD Touch screen
Cooling System	Water circulation cooling system	Cooling System	Cooling System	Internal water to air heat exchanger
Electrical Power	AC 100-127/200-240V, 50/60Hz	120VAC 10A, 50/60Hz	Not Publicly Available	AC 230V, 50Hz
Beam Delivery System	Articulated Arm with Handpiece	Articulated Arm with Handpiece	Articulated arm with handpiece	Articulated arm with handpiece

System dimension	1045 mm×540 mm×1600 mm	97cm H x 48cm W x 97cm D	Not Publicly Available	93 cm × 40 cm × 93 cm
System Weight (kg)	186 kg	130kg	Not Publicly Available	128kg

Analysis:

From the comparison table, the subject devices and predicate device have the same Intended use & Indications for Use, applicable place.

(1) The spot-sizes for the indicated treatment mode are not publicly available of the Predicate Device K200116. The spot-sizes of subject device are available for all the treatment modes. Same as the reference device K233007 and K220268.

(2) The Maximum Average Fluence of the K200116 is not publicly available.
The subject device has a pulse width ranging from 300 - 500ps, 15.9 J/cm^2 @ 1064nm and 8 J/cm^2 @ 532nm for 2mm spot.
The first reference device, K233007, has a pulse width 300ps. Its Maximum Fluence/minimum spot size/Pulse width values are 15.92 J/cm^2 @ 1064nm and 8 J/cm^2 @ 532nm for 2mm spot.
The second reference device, K220268, with a pulse width 500ps. Its Maximum Fluence/minimum spot size/Pulse width values of 15.5 J/cm^2 @ 1064nm and 8 J/cm^2 @ 532nm for 2mm spot.
The Maximum Average Fluence of two reference devices could covering the range of the subject device. It can be considered that the propose device can achieve its intended use and is safety.

(3) Aiming Beam of the Primary Predicate Device is not publicly available. The subject device has the similar aiming beam with reference device K233007 and K220268. The difference in the parameter of aiming Beam will not raise new safety issues of the proposed device. And the proposed device has passed the IEC60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test and IEC 60825-1 test, the safety and performance of the product can be ensured. Therefore, this difference will not affect the safety and effectiveness.

7.0 **Non-Clinical Test Conclusion**

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

- IEC 60601-1:2005/AMD2:2020 Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC/TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.
- IEC 60601-2-22:2019, 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
- ISO10993-10:2021 Biological evaluation of medical devices -- Part 10: Tests for skin sensitization
- ISO10993-23:2021 Biological evaluation of medical devices -- Part 23: Tests for irritation

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”

8.0 **Clinical Test Conclusion**

No clinical study is included in this submission.

9.0 **Conclusion**

Performance testing contained in this submission demonstrates the minor differences in technological characteristics between the subject device and the predicate do not raise different questions of safety and effectiveness. And based on the performance testing and compliance with acceptable voluntary standards, we believe the subject device is substantially equivalent to its predicate device.