April 30, 2024

Smedtrum Medical Technology Co., Ltd.
Crimson Wu
Senior Regulatory Engineer
1F., No. 8, Ln. 97, Wugong Rd.,
New Taipei City, Xinzhuang Dist. 248016
Taiwan

Re: K240118
Trade/Device Name: Picosecond Nd:YAG 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: March 29, 2024
Received: March 29, 2024

Dear Crimson Wu:

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.

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: 2024.04.30 11:46:33 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240118

Device Name
Picosecond Nd:YAG Laser System

Indications for Use *(Describe)*
The Picosecond Nd: YAG Laser System is intended for use in surgical and aesthetic application in the medical dermatology and general and plastic surgery: such as tattoos removal and benign pigmented lesions.

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

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K240118, 510(k) Summary
Picosecond Nd:YAG Laser System

I. SUBMITTER

Smedtrum Medical Technology Co., Ltd.
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Xinzhuang Dist., New Taipei City 248016,
Taiwan (R.O.C.)

Contact Person

Crimson Wu
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E-mail: crimsonwu@smedtrum.com
Date of preparation: Jan 16th, 2024

II. DEVICE

Trade Name:	Picosecond Nd:YAG Laser System
Common or Usual Name:	Surgical Laser Device
Product code:	GEX
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology 21 C.F.R. § 878.4810, Device Class II

III. PREDICATE DEVICE

Manufacturer	Shanghai Apolo Medical Technology Co., Ltd.
Trade Name:	PicoSecond Nd: YAG Laser System
Common or Usual Name:	Surgical Laser Device
Regulation Name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology 21 C.F.R. § 878.4810, Device Class II
Premarket Notification:	K200116　May 28th, 2020

IV. DEVICE DESCRIPTION

Picosecond Nd:YAG Laser Systems, pulse width: <500ps; pulse energy up to 500mJ, instantaneous emission of laser energy efficient crushing lesions tissue chromophore, that is photon burst: laser accumulation energy is instantaneous emission. The instrument uses the laser-wave to break Chromatophore into pieces which can be

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naturally absorbed by the body. So that it achieves the purpose of de-freckling. The 1064 nm wavelength will shatter and removes the black, blue, purple and brown pigments while the 532 nm wavelength will shatter and removes red, pink, yellow and orange pigments of the tattoo or other pigmentations without damaging the normal tissue. Apply for tattoo and tattoo epidermal/ dermal lesion pigmented, lesions removal. Picosecond laser is being introduced as the first safe and effective aesthetic laser specifically designed to treat tattoos and pigmented lesions. This innovative laser delivers ultra short pulse bursts of energy to the skin in trillionths of a second. These pulses create a photomechanical effect, that target ink while avoiding unmarked tissue. The pulse shatters the ink into tiny, dust-like particles which are easily eliminated by the body.

V. INDICATIONS FOR USE

The Picosecond Nd: YAG Laser System is intended for use in surgical and aesthetic application in the medical dermatology and general and plastic surgery: such as tattoos removal and benign pigmented lesions.

1064nm wavelength:

- Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, blue, green 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.

VI. COMPARISON OF TECHNOLOGICAL CHARATERISTICS WITH THE PREDICATE DEVICE

Feature	**Proposed device**	**Predicate device (K200116)**
Device Name	Picosecond Nd:YAG Laser System	PicoSecond Nd: YAG Laser System
Product Code	GEX	GEX
Regulation No.	21 CFR 878.4810	21 CFR 878.4810
Device Class	Class II	Class II

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

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Feature	**Proposed device**		**Predicate device (K200116)**	
			benign pigmented lesions on Fitzpatrick skin types I-IV.	
Laser Type	GaA1As Diode Laser array		GaA1As Diode Laser array	
Laser Classification	Class IV		Class IV	
Laser Wavelength	532 nm and 1064 nm		532 nm and 1064 nm	
Laser Delivery System	Articulated arm		Articulated arm	
Laser firing Controls	LCD color Touchscreen Footswitch		LCD color Touchscreen Footswitch	
Pulse energy	532 nm	1064 nm	532 nm	1064 nm
	250 mJ	500 mJ	250 mJ	500 mJ
Frequency	1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Hz (10 adjustable levels)		1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Hz (10 adjustable levels)	
Pulse width (Max)	300~500 ps		300~500 ps	
Spot Size	Adjustable spot size 2~10 mm		Adjustable spot size 2~10 mm	

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Feature	**Proposed device**	**Predicate device (K200116)**
Cooling	water + air + TEC	water + air + TEC

VII. PERFORMANCE DATA

The Picosecond Nd:YAG Laser System has been determined through engineering testing to verify laser energy output and electrical safety.

Electrical safety and electromagnetic compatibility

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 60601-1-2:2020 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and requirements

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

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was 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." The software for this device was considered as a "moderate" level of concern since a failure of the software could result in minor injury to a patient or to a user of the device.

Sterilization and Shelf-Life

The proposed device is not provided sterile and does not need to be sterilized. The handpiece and the body are cleaned with a soft cloth moistened with ethanol of 70% strength or higher. The proposed device is reusable and does not have a restricted shelf-life.

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Bench testing

Bench testing was conducted to validate that the laser output energy is within ±20%. Laser energy meter is the instrument for measuring laser energy output which meets IEC 60825. Not only energy but also frequency, pulse width and spot size are consistent with the specification which are under predicate products' specification. Spectrum Analyzer is for wavelength (532 nm/ 1064 nm) checking, Oscilloscope is for frequency and pulse width, then we emitted laser on the photo paper and use ruler to check the size of spots.

VIII. CONCLUSION

The Picosecond Nd:YAG Laser System has the same intended use, similar indications for use, the same technological characteristics, the same energy used, and the same operating principles as its predicates. The non-clinical data and performance testing reports in this submission demonstrate that Picosecond Nd:YAG Laser System meets the expected performance requirements. Any difference between the subject and predicate device do not raise new issues of safety or effectiveness. Based on above analysis, the Picosecond Nd:YAG Laser System is as safe, as effective, and performs as well as the cited predicate device.