April 9, 2026

Shanghai Apolo Medical Technology Co., Ltd.
Felix Li
RA Supervisor
Bldg. 11, Lane 1566, Nanle Rd., Songjiang District
Shanghai, 201613
China

Re: K260017
Trade/Device Name: Picosecond Nd:YAG Laser Systems (HS-298)
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: January 4, 2026
Received: January 5, 2026

Dear Felix Li:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.04.09 15:01:04 -04'00'

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260017

Device Name
Picosecond Nd:YAG Laser Systems (HS-298)

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 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.

510(k) #: K260017

510(k) Summary

Prepared on: 2026-04-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shanghai Apolo Medical Technology Co., Ltd.
Applicant Address	Building 11, Lane 1566, Nanle Road, Songjiang District Shanghai Shanghai 201613 China
Applicant Contact Telephone	+86-2134622015
Applicant Contact	Mr. Felix Li
Applicant Contact Email	liqiang@apolo.com.cn

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Picosecond Nd:YAG Laser Systems (HS-298)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code(s)	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200116	PicoSecond Nd: YAG Laser System	GEX
K241144	Picosecond Nd:YAG Laser (PICOCAREMAJESTY)	GEX
K234104	PICOANDY (Q-Switched Nd:YAG Laser)	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The Picosecond Nd: YAG Laser System (HS-298) is a Nd: YAG solid state laser, which can deliver the energy at picosecond pulse bursts to the skin. The system is composed of laser generator, articulated arm, handpiece, laser power supply, cooling system, display and control system.

The Picosecond Nd: YAG Laser System produces a pulsed beam of coherent near infrared (1064nm) and visible (532nm) light. This beam is directed to the treatment zone by means of an articulated arm coupled to a Zoom handpiece, MLA handpiece, or DOE handpiece. The outputs of the two lasers are designed to be co linear on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either the 532 nm or 1064nm wavelengths.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 benign pigmented lesions on Fitzpatrick skin types I-IV.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the proposed device are the same as the predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The wavelengths (532nm, 1064nm) of the subject device are the same as the predicate devices K200116, K241144 and K234104.

The maximum output energy of Zoom handpiece (532nm,1064nm) is 250mJ and 500mJ respectively and is the same as predicate device K200116. The maximum output energy of MLA handpiece (532nm,1064nm) is 200mJ and 500mJ respectively, which is covered by the predicate devices K241144 (250mJ and 500mJ) and K234104(200mJ and 550mJ).The maximum output energy of DOE handpiece (532,1064nm) is 200mJ and 450mJ respectively, which is the same as the predicate K241144 (200mJ and 450mJ) and covered by the predicate device K234104 (200mJ and 550mJ).

The pulse duration of the Zoom handpiece (532nm,1064nm) is 300-500ps, which is the same as the predicate K200116. The pulse duration of the MLA/DOE handpiece (532nm,1064nm) is 300-500ps, which is similar to the predicate device K234104 (350ps-550ps), the minor difference does not affect the safety and effectiveness of the device.

The repetition rate of Zoom handpiece (532nm, 1064nm) is 1-10Hz, which is the same as the predicate device K200116. The repetition rate of MLA/DOE handpiece (532nm, 1064nm) is 1-10Hz, which is the same as the predicate devices K241144 and K234104.

The spot size of Zoom handpiece (532nm, 1064nm) is 2-10mm, which is the same as the predicate device K200116. The spot size of MLA handpiece (532nm, 1064nm) is 10mm, which is covered by the predicate devices K241144 (2-10mm) and K234104 (2-10mm). The spot size of DOE handpiece (532nm, 1064nm) is 6mm, which is covered by the predicate devices K241144 (2-10mm) and K234104 (2-10mm).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Testing:
A battery of tests was performed to verify that the proposed device met all design specification. The test result demonstrated that the proposed device complies with the following standards:
Electrical safety and electromagnetic compatibility
IEC 60601-1: 2005+A1:2012+ A2:2020 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 disturbances - Requirements and tests
IEC 60601-2-22:2019 Medical electrical equipment - Part 2-22: Particular requirements for the 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

Performance testing on energy output, pulse width, wavelength, spot size and repetition rate.

Clinical Testing:
It is not applicable.

Conclusions:
Base on the performance testing and validation studies that the subject device is substantially equivalent to the predicate devices.