October 23, 2025

RiSu Medical Technology Co., Ltd.
Tianqiang Yu
Management Representative
Rm 201, Bldg 11, Western Cloud Valley(Phase III),
the intercection of Kangding Road and Tongwen Road
Fengxi New City of Xixian New Area, Shaanxi Province 712000
China

Re: K252345
Trade/Device Name: Picosecond Laser Device (PF131-BI)
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 25, 2025
Received: July 28, 2025

Dear Tianqiang Yu:

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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.10.23 14:44:17 -04'00'

for 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)*
K252345

Device Name
Picosecond Laser Device (PF131-BI)

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.

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

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510(k) #: K252345

510(k) Summary

Prepared on: 2025-10-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	RiSu Medical Technology Co., Ltd.
Applicant Address	Rm 201, Bldg 11, Western Cloud Valley(Phase III), the intercection of Kangding Road and Tongwen Road Fengxi New City of Xixian New Area Shaanxi Province 712000 China
Applicant Contact Telephone	+86 10 808 9960
Applicant Contact	Mr. Tianqiang Yu
Applicant Contact Email	info@truthful.com.cn

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Picosecond Laser Device (PF131-BI)
Common Name	Powered Laser Surgical Instrument
Classification Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
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
K191685	PicoWay Laser System	GEX
K233007	PICO LEGEND Nd:YAG Laser System	GEX
K220268	Picosecond Laser System	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The Picosecond Laser Device mainly consists of a main unit, a light guide arm, a standard handpiece, a foot switch, a power cord, and other auxiliary treatment accessories.
The main unit includes power supply unit, control unit, laser system, water circulation cooling system.
Accessories include goggles, eye mask, funnel assembly, drainage nozzle, fuse tubes, remote control interlock connector, and keys.
The Picosecond Laser Device is a multi-wavelength, pulsed laser system designed for the treatment of benign pigmented lesions. A key feature of the device is its ability to produce multiple laser wavelengths (1064 nm and 532 nm).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

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

The proposed device has the same indications for use as the predicate device, K200116.

Technological Comparison 21 CFR 807.92(a)(6)

• The wavelengths (532nm and 1064nm) of the subject device are the same as the wavelengths of all predicate and reference devices.
• The pulse duration of the subject device (300-500ps) is the same as K200116.
• The pulse energy of the subject device (532nm: 100-500 mJ, adjustable by 50 mJ; 1064nm: 50-250 mJ, adjustable by 25 mJ) is the same as K233007.
• The spot sizes of subject device (2mm-10mm, +/- 20%, step by 1mm) are the same as K233007 and K220268.
• The Maximum Average Fluence of the subject device 15.91 J/cm2 @ 1064nm and 7.95 J/cm2 @ 532nm for 2mm spot is similar to K233007 (15.92 J/cm^2@ 1064nm and 7.96 J/cm^2 @ 532nm for 2mm spot) and K220268 (15.5 J/cm^2@ 1064nm and 8 J/cm^2 @ 532nm for 2mm spot).
• The repetition rate of the subject device (1-10 Hz, 1 Hz step) is the same as all predicate and reference devices.
• The Aiming Beam wavelength (650nm) of the subject device is similar to the aiming beam wavelength of K233007 (635nm) and K220268 (635nm).

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

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

The analysis and tests above demonstrate that the subject device is as safe, as effective, and performs as well as the predicate devices.