Shanghai Bele Medical Technology Co.,Ltd
Jeremy Li
General Manager
Room 402, 4F, Building 1, NO.3255 Shengang Road,
Songjiang District
Shanghai, Shanghai 201600
China

Re: K240386
Trade/Device Name: Picosecond Nd:YAG Laser Systems (BL-C10)
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: February 5, 2024
Received: February 8, 2024

Dear Jeremy 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 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,

Yan Fu -S
Digitally signed by Yan Fu -S
Date: 2024.05.16 21:17:35 -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.

Submission Number *(if known)*

K240386

Device Name

Picosecond Nd:YAG Laser Systems (BL-C10)

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) #: K240386

510(k) Summary

Prepared on: 2024-05-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	SHANGHAI BELE MEDICAL TECHNOLOGY CO.,LTD
Applicant Address	Room 402, 4F, Building 1, NO.3255 Shengang Road, Songjiang District Shanghai Shanghai 201600 China
Applicant Contact Telephone	+86-21 51012882
Applicant Contact	Jeremy Li
Applicant Contact Email	jeremy@belemed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Picosecond Nd:YAG Laser Systems (BL-C10)
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
K233018	PICOSECOND Nd: YAG Laser System	GEX
K191685	PicoWay Laser System	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The BL-C10 Picosecond ND:YAG Laser Systems is designed with a mains electricity (AC-powered) light amplification by stimulated emission of radiation (LASER) device assembly based on neodymium-doped yttrium-aluminium-garnet (Nd:YAG) and frequency-doubled Nd:YAG laser technology. The laser system generates ultra-short pulses in the picosecond range (1 picosecond = 10^-12 seconds). The pulses are then amplified within the Nd:YAG crystal. The system operates at two wavelengths: 1064nm and 532nm. These wavelengths are chosen to target different colors of pigments in tattoos and pigmented lesions.
- 1064nm Wavelength: Used for treating tattoos with colors like black, brown, green, blue, and purple, as well as for treating benign pigmented lesions.
- 532nm Wavelength: Used for removing tattoos with colors such as red, yellow, and orange, and for treating benign pigmented lesions.
The ultra-short pulses have very high peak power, allowing them to interact with target (tattoos or pigmented lesions) in a precise and controlled manner. The short duration of the pulses helps minimize heat buildup in surrounding tissues.

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 indication of the proposed device is covered by the predicate.

Technological Comparison 21 CFR 807.92(a)(6)

The technical characteristics of the subject device are the same as the predicate (including wavelengths, maximum pulse energy, repetition rate, spot size, beam delivery), except for the following parameters:
- Difference 1: The pulse duration of the subject device is 300-500ps; the pulse duration of the predicate device is 300ps – both modes. The pulse duration differs slightly, however, the pulse duration of the subject device is within the range of the reference, K191685, which is 240-500ps.
- Difference 2: The subject device has a one handpiece (532nm and 1064 nm); the primary predicate has a one handpiece for 532nm and 1064 nm; the secondary predicate has three types of hand pieces Resolve (532 nm, 532 nm high energy, 1064 nm) indicated for wrinkle treatment, Resolve Fusion (532nm and 1064nm) indicated for treatment of benign pigmented lesion and Zoom (532nm and 1064nm) for tattoo removal and benign pigmented lesion treatment. The subject device has fewer handpieces than the secondary predicate, however, the handpiece in the subject device is the same as two handpieces of the predicates.
- Difference 3&4&5: system dimension, system weight, and electrical power supply. The subject device's dimension (1070mm x 600mm x 1250mm), weight (120kg) and power supply (110-240V AC, 10A, 50/60 Hz) are slightly different from the reference device K191685, dimension (1070 mm x 46mm x 690 mm), weight 12kg, power supply (220-240 V AC, 30A, 50/600 Hz) (the parameters of the predicate are unknown). However, the difference does not affect the device function. The subject has passed the IEC 60601-1, IEC 60601-1-2 tests, and the test results show that the device can function as intended.

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+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 disturbances - Requirements and tests
IEC TR 60601-4-2: 2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC 60601-2-22:2007+A1: 2012 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

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 device.