February 3, 2026

Xi'an Taibo Laser Beauty Company
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Rm. 1801, # 161 E. Lu Jiazui Rd., Pudong
Shanghai, 200120
China

Re: K252048
Trade/Device Name: 808nm Semiconductor Laser Hair Removal Machine
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: June 30, 2025
Received: June 30, 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: 2026.02.03 19:43:38 -05'00'

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)*
K252048

Device Name
808nm semiconductor laser hair removal machine

Indications for Use *(Describe)*
The 808nm Semiconductor laser hair removal machine is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

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

K252048

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:	Xi'an Taibo Laser Beauty Company
Address:	3rd Floor, No.1 Factory Building, No.1787, Caotan 10 Road, Economic and Technological Development Zone, Xi'an, Shaanxi, China
Tel:	+86-13401026958
Contact:	Wang Shuai

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: Dec.1, 2025

2.0 Device Information

Trade name:	808nm semiconductor laser hair removal machine
Common name:	Powered Laser Surgical Instrument
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Model:	TBSL-U-20-8-02
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: Shandong Moonlight Electronics Tech Co., Ltd.
Trade/Device Name: Medical Diode Laser Hair Removal System
510(k) number: K250431

Reference Device:

Manufacturer: Beijing LaserTell Medical Co., Ltd.
Trade/Device Name: Diode Laser Therapy Systems
510(k) number: K220381

4.0 Device Description

This 808nm semiconductor laser hair removal machine adopts 808nm semi-conductor laser, based on selective photothermolysis principle, through specific wavelength, penetrate epidermis into dermis, optical energy was absorbed and translated into heat energy with restraining hair follicle tissues, and produce photothermal effect. It takes laser energy in hair follicle with rich in melanin, surrounding tissues absorb less even no energy, reach to restrained melanin of hair follicles and remove hair. The Medical Diode Laser Hair Removal System utilize a semiconductor diode with invisible infrared radiation as a laser source to emit 808nm wavelength laser which is absorbed by melanin. The laser power is delivered to the treatment area via laser handpiece. The emission laser is activated by a foot-switch.

This 808nm semiconductor laser hair removal machine consists of laser power supply, laser treatment handle, host controller, liquid crystal controller (operating system) water cooling system, low voltage control circuit and fault alarm system. Accessories include water filling funnel, overflow plug, foot switch, bracket, key, laser protection goggles (operator wearing), protective eye wear (patient wearing), power line, fuse, user manual and packing list.

5.0 Indication for Use Statement

The 808nm Semiconductor laser hair removal machine is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

6.0 Comparison to the Predicate Device

Item	Subject device Model: TBSL-U-20-8-02	Predicate device K250431 Model: MNLT-D1	Reference device K220381 Model: AlexMED Pro	Remark
Trade/Device Name	808nm semiconductor laser hair removal machine	Medical Diode Laser Hair Removal System	Diode Laser Therapy Systems	/
Manufacturer	Xi'an Taibo Laser Beauty Company	Shandong Moonlight Electronics Tech Co.,Ltd.	Beijing LaserTell Medical Co., Ltd.	/
Class &Code	Class II GEX 878.4810	Class II GEX 878.4810	Class II GEX 878.4810	Same
Intended Use/Indication for Use	The 808nm Semiconductor laser hair removal machine is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	The Medical Diode Laser Hair Removal System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	The Diode Laser Therapy Systems is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	Same
Configuration	Main Unit Handpiece Foot Control	Main Unit Handpiece Foot Control	Main Unit Handpiece	Same

Principle of Operation	Semiconductor laser	Diode Laser	Diode Laser	Same
Laser Type	Diode Laser	Diode Laser	Diode Laser	Same
Laser Classification	Class IV	Class IV	Class IV	Same
Laser wavelength	808 nm	808 nm	808 nm	Same
Spot Size	12 mm × 36mm	12mm × 21mm	15mm × 15mm	Analysis 1
Fluence	1~32.4 J/cm^2	1-65 J/cm^2	0-100 J/cm^2	Analysis 2
Frequency	1-10 Hz	1-10 Hz	1-10 Hz	Same
Pulse Duration	10-75ms	10-320ms	1-300 ms	Analysis 3
Power Supply	110-220V~50Hz/60Hz, 2000W	AC 110V, 50Hz/60Hz	110-230 VAC/50Hz-60Hz, 2000W	Analysis 4
Dimension	45 cm × 50 cm × 125 cm	1180×465×465mm	560mm×380mm×1180mm	Analysis 4
Weight	45kg	74kg	60 kg	Analysis 4
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Same

EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Same
Patient Direct/Indirect Contact Materials	ABS engineering plastics, aluminum and surface sandblasting oxidation treatment, quartz light guide wave plate	Aluminum and Gemstone	Unpublished	Analysis 5
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No evidence of sensitization	No evidence of sensitization	No evidence of sensitization	Same
Irritation	No evidence of irritation	No evidence of irritation	No evidence of irritation	Same
Biocompatibility testing standards	Comply with ISO 10993-5, ISO 10993-10, ISO 10993-23	Comply with ISO 10993-5, ISO 10993-10, ISO 10993-23	Comply with ISO 10993-5, ISO 10993-10	Same

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

Analysis 1:

The proposed device is different in Spot Size from the predicate, Spot size only affects the area of treatment, not affect the therapeutic effect. Therefore, this difference will not affect the safety and effectiveness.

Analysis 2:

The proposed device only has slight difference in Fluence with the predicate device. The fluence of the proposed device is within the allowable error range of the predicate device, which can justify that the difference in the parameter of fluence will not raise new safety issues of the proposed device. And the bench tests conducted on the proposed device is same with the predicate device, the results of which could support the substantially equivalency with predicate device. So the slight difference is considered to have no effect on effectiveness and safety.

Analysis 3:

The proposed device is difference in Pulse Duration with the predicate device. The pulse duration of the proposed device is within the range of that of the predicate device, which is similar to the proposed device's pulse duration, so this difference will not affect safety and effectiveness of the proposed device.

Analysis 4:

The proposed device is different in Power Supply, Dimension and Weight from the predicate device. However, the power supply, dimension and weight difference are just in physical specification and this difference will not raise any issues in safety and effectiveness. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Reference Device K220381’s power is 2000 W, which is identical to our device’s peak active power of 2000 W.

Therefore, this difference will not affect the safety and effectiveness.

Analysis 5:

The proposed device is different in Electrical Safety Testing Standard and Biocompatibility Testing Standard from the predicate device. The proposed device was tested according to IEC 60601-1:2020, ISO 10993-5:2009, ISO 10993-10:2021 and ISO 10993-23:2021, which are FDA recognized standard. Therefore, this different will not affect safety and effectiveness of the proposed device.

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 60601-1-6:2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- 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:
Consistent with **Basic Documentation,** software validation was conducted in accordance with the be FDA June 2023 document “Content of Premarket Submissions for Device Software Functions”.

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.