February 23, 2026

Shenzhen Mlay Intelligent Technology Co., Ltd.
Libin Liu
General Manager
201, 301, Bldg. 28, Cuigang Industrial Zone 2
Huaide Community, Fuyong St., Baoan District
Shenzhen, Guangdong 518103
China

Re: K253666
Trade/Device Name: IPL Hair Removal Device (Models: T31A, T32A)
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: OHT
Dated: November 20, 2025
Received: November 21, 2025

Dear Libin Liu:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.02.23 16:41:49 -05'00'

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)*
K253666

Device Name
IPL Hair Removal Device (Models: T31A, T32A)

Indications for Use *(Describe)*
The IPL Hair Removal Device is an over-the-counter device indicated for the removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long term, stable reduction in the amount of hair 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.

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

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K253666

510(k) Summary

Prepared on: 2026-02-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shenzhen Mlay Intelligent Technology Co.,Ltd.
Applicant Address	201, 301, Building 28, Cuigang Industrial Zone 2, Huaide Community, Fuyong Street, Baoan District, Shenzhen City, Guangdong Province, China. Shenzhen 518103 China
Applicant Contact Telephone	+86 18344147065
Applicant Contact	Mr. LIBIN LIU
Applicant Contact Email	wuxiaotian@mlays.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	IPL Hair Removal Device (Models: T31A, T32A)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Light Based Over-The-Counter Hair Removal
Regulation Number	878.4810
Product Code(s)	OHT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K250942	Ice Cooling IPL Hair Removal Device (UI20S DB, UI20S RE, UI20S PW, UI20S GP, UI20S GR, UI20S BK, UI20 DB, UI20 RE, UI20 PW, UI20 GP, UI20 GR, UI20 BK)	OHT
K241998	Ice Cooling IPL Hair Removal Device (UI20 DB, UI20 RE, UI20 GP, UI20 PW, UI20S DB, UI20S RE, UI20S PW, UI20S GP,UI20 WH, UI20 GR, UI20 BS, UI20 MP, UI20 BL, UI20 PN, UI20 BR, UI20WG, UI20S WH, UI20S GR, UI20S BS, UI20S MP)	OHT
K251176	IPL Hair Removal Device (Model(s): T14B,T16B,T19B, T15B,T17C,T18B, T21A,T21B,T21C, T21D,T22A,T22B, T25B,T25C)	OHT

Device Description Summary

21 CFR 807.92(a)(4)

The IPL Hair Removal Device is a personal, light-based, hair reduction device intended to be sold over-the-counter directly to the end user.
The device provides hair reduction using Intense Pulsed Light technology and cooling technology (suitable for model T31A, T32A)
The Intense Pulsed Light technology works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain. The device is only powered by the external power adapter and its IPL emission activation is by finger switch. The device contains a Quartz glass Xenon lamp and a skin sensor to detect appropriate skin contact. If the device is not properly and fully applied to the skin of the treatment area, the device will not emit light pulses; If the device is properly and fully applied to the skin of the treatment area, the device can emit light pulses in as quickly as 0.5 seconds. In automatic mode, it supports continuous flashing and

automatic light emission. It is designed with dual lamps that work together and can emit mutipulses per shot.
In auto-recognition skin color mode, the skin tone sensor can detect and identify the color of skin, and determine the required intensity based on the recognized skin color. Make sure the skin tone sensor is in full contact with the skin. If a valid skin color is detected, the corresponding energy level is displayed. If it is not in full contact with the skin, the energy level is 0 and no light pulses are emitted.
The cooling technology based on the temperature difference electrical phenomenon through the semiconductor cooling chip inside the IPL main device and uses the principle of the Peltier effect to achieve the purpose of cooling function. The cooling panel is constructed with sapphire, and does not affect the irradiated area (spot size) of the light outlet.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The IPL Hair Removal Device is an over-the-counter device indicated for the removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long term, stable reduction in the amount of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device is the same as the predicate device's, the contents as below:
The Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs.

Technological Comparison

21 CFR 807.92(a)(6)

The IPL Hair Removal Device has the same intended use, energy medium (Xenon Arc Flashlamp), and similar operational characteristics as the predicate devices.
The wavelength range (510-1200nm) is the same as K251176.
The maximum fluence 6.48J/cm2 is within range of those of the predicate devices (K251176, 5.90J/cm2; K250942, 6.92J/cm2).
The spot size 5.4 cm2 is larger than the that of the predicate devices (e.g., K250942, 3.9cm2) but does not raise different questions in safety or effectiveness.
The pulse duration (0.4ms – 0.92ms multipulse) is within the range of those of the predicate devices (K250942, 0.86-6.32ms, double pulse, quadruple pulse; K251176, 0.4-5.5ms).
Any minor differences between the subject device and the listed predicate devices do no raise any issues of safety or effectiveness. Performance data supports that the device is as safe and as effective as the predicate device for its intended use. Therefore, the IPL Hair Removal Device (Models: T31A, T32A) is substantially equivalent to its predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

1)Biocompatibility Testing
The biocompatibility evaluation for the body-contacting components of the subject device was conducted in accordance with the "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within a Risk Management Process", as recommehded by FDA. The battery of testing was performed to, and passed, including:
ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
The biocompatibility evaluation described above was conducted on a device model with the same body-contacting materials, material sources (from the same manufacturer), and contact nature as the subject device for this registration. The production process is only different in terms of the molds, which does not involve changes to material composition. Although there are minor differences in production processes, no pollutants or residues are generated or introduced during production. Therefore, the biocompatibility data from the tested model can be directly referenced to demonstrate that the subject device also possesses excellent biocompatibility and will not pose biological hazards to the human body.

2)Electrical Safety and EMC Safety
Electrical safety and Eye safety testing was performed to, and passed, the following standards:
IEC 60601-1Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-2-57 Edition 1.0 2011-01 Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic diagnostic monitoring and cosmetic/aesthetic use

IEC 60601-2-83:2019/AMD1:2022 Medical Electrical Equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

3)Eye Safety
IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems

4)Software Verification and Validation
In this 510(k) submission, the software documentation are the basic documentation. System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

Summary
Based on the above performance as documented in this application, the subject device IPL Hair Removal Device was found to have a safety and effectiveness profile that is similar to the predicate device.

Conclusion
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the subject device IPL Hair Removal Device (Models: T31A, T32A) is to be concluded substantially equivalent to its predicate devices.