



March 8, 2024

Shenzhen Mlay Intelligent Technology Co., Ltd.
Liu Libin
General Manager
302,401, Building 1, No. 2, Xiashiwei Road, Huaide
Community, Fuyong Street, Baoan District
Shenzhen, 518000
China

Re: K240264

Trade/Device Name: Home Use Hair Removal Device (Model(s):T10A, T10B, T10C, T10D, T11A, T15A, T17A, T18A, T14A, T16A, T19A)

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: January 31, 2024

Received: January 31, 2024

Dear Liu Libin:

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,

Tanisha L. Tanisha L. Hithe -S
Hithe -S 2024.03.08
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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

Indications for Use

510(k) Number (if known)

K240264

Device Name

Home Use Hair Removal Device (Model(s):T10A, T10B, T10C, T10D, T11A, T15A, T17A, T18A, T14A, T16A, T19A)

Indications for Use (Describe)

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, in patients with Fitzpatrick Skin Phototypes I-V.

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) Summary

"510(k) Summary" as required by 21 CFR Part 807.92.

1. Submitter Information

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2. Device Information

Trade name: Home use hair removal device
Model(s): T10A, T10B, T10C, T10D, T11A, T15A, T17A, T18A, T14A, T16A, T19A
Common Name: Light Based Over-The-Counter Hair Removal
Regulation Class: Class II
Product Code: OHT
Review Panel: General & Plastic Surgery
Regulation Number: 21CFR 878.4810
Regulation Description: Laser surgical instrument for use in general and plastic surgery
Submission Type: Traditional 510(k)

3. Predicate Device

Manufacturer	Predicate Device	510k Number	Decision Date
Shenzhen Mareal Tech Co., Ltd	Home use hair removal device, Model(s): T4, T5, T8, T4-01, T5-01, T8-01, T7	K220248	Jul.01, 2022

4. Device Description

The Home use 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. It 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 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.

5. Indications for Use

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, in patients with Fitzpatrick Skin Phototypes I-V.

6. Comparison of Technological Characteristics With the Predicate Device

The Home use hair removal device has the same intended use, mode of action and similar operational characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate devices do not raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use. Therefore, the Home use hair removal device may be found substantially equivalent to its predicate device.

Home use hair removal device is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance:

Comparison Elements	Subject Device	Predicate Device K220248
K Number	Pending	K220248
Trade name	Home use hair removal device, Model(s): T10A, T10B, T10C, T10D, T11A, T15A, T17A, T18A, T14A, T16A, T19A	Home use hair removal device, Model(s): T4, T5, T8, T4-01, T5-01, T8-01, T7
Location for use	OTC	OTC
Wavelength range	510~1200nm	530-1100nm
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Light Source	Intense Pulsed Light	Intense Pulsed Light
Pulsing control	Finger switch	Finger switch
Delivery device	Direct illumination tissue	Direct illumination tissue
Energy density	1.37~5.23J/cm ²	2.0~4.3J/cm ²
Spot size	3.5cm ² , 3.9cm ²	3.5cm ² , 3.9cm ²
Pulse duration	0.5~8.0ms	5.0~9.6ms
Indication for use / intended use	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 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, in patients with Fitzpatrick Skin Phototypes I-V.	the chin line and large areas such as legs, in patients with Fitzpatrick Skin Phototypes I-V.
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7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

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 recognized by FDA. The battery of testing was performed to, and passed, including:

- ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation

2) Electrical Safety and Eye Safety

Electrical safety and Eye safety testing was performed to, and passed, the following standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-11 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 60601-1-11:2015 MOD) [Including Amendment1 (2021)]
- IEC 60601-2-57 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 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 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 Home use hair removal device was found to have a safety and effectiveness profile that is similar to the predicate device.

8. 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 Home use hair removal device is to be concluded substantial equivalent to its predicate devices.