July 1, 2022

Shenzhen Mareal Tech Co., Ltd
% Rain Yip
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm2401, ZhenYe International Center, No.3101-90
Qianhai Road, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K220248
Trade/Device Name: Home use hair removal device
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 20, 2022
Received: January 31, 2022

Dear Rain Yip:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jianting Wang
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220248

Device Name
Home use hair removal device, Model(s): T4, T5, T8, T4-01, T5-01, T8-01, T7

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.

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510(k) Summary

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

Date: 2022-01-20

I. Submitter

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II. Device

Name of Device: Home use hair removal device
Model(s): T4, T5, T8, T4-01, T5-01, T8-01, T7
Common or Usual Name: Light Based Over-The-Counter For Hair Removal
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHT
Regulation Number: 21 CFR 878.4810

III. Predicate Device

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Mismon Technology Co., Ltd.	Home Use IPL Beauty Device/MS-208B	K210311	Jul.23, 21

IV. 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.

The proposed Home use hair removal devices in this 510(k) are the T4, T5, T8, T4-01, T5-01, T8-01, and T7 models. Their intended use, performance, structure, design, and operation are similar or identical to the predicate device, with differences being product appearance and size (included the spot size of the treatment window), display contents (mainly as the symbol of treatment level) and pulse duration. The model difference is embodied in: #1) the spot size of the T7 is 3.9cm^2, and that of other models is 3.5cm^2; #2) T7 uses a fans-shaped to represent the symbol of the treatment level, while other models use rectangles-shaped to represent; and the above differences do not affect or change the intended use of the device; #3) the pulse duration of the T7 is 5.0~7.0ms, and that of other models is 7.6~9.6ms.

V. 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.

VI. 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 device. Any minor differences between the subject device and the listed predicate device do no 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 device in terms of intended use, design, material, specifications, and performance:

Comparison Elements	**Subject Device**	**Predicate Device K210311**
K Number	Pending	K210311
Trade name	Home use hair removal device Model(s): T4, T5, T8, T4-01, T5-01, T8-01, T7	Home Use IPL Beauty Device, Model MS-208B
Wavelength range	530-1100nm	510-1100nm
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Energy density	2.0~4.3 J/cm²	2.6~5.1 J/cm²
Spot size	3.5cm², 3.9cm²	3.6cm²
Pulse duration	5.0~9.6ms	9~12ms
Pulsing control	Finger switch	Finger switch
Delivery device	Direct illumination tissue	Direct illumination tissue
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	The Home Use IPL Beauty Device is an over-the-counter device intended for removal of unwanted hair such as

Comparison Elements	**Subject Device**	**Predicate Device K210311**
	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.	but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs.
Location for use	OTC	OTC

VII. 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 –Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices –Par t 10: Tests for Irritation and Skin Sensitization

2) Electrical Safety and Eye Safety

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

- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- 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: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- IEC 60601-2-57 Medical electrical equipment –Part 2-57: Particular requirements for the basic safety and essential performance of non-laser 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

Software documentation consistent with ***moderate level*** of concern was submitted in this 510(k). 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.

VIII. Conclusions

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 concluded to be substantially equivalent to its predicate device.