March 19, 2025

Mustech Electronics Co., Limited
% Riley Chen
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K250131
Trade/Device Name: IPL Hair Removal Device (M8011, M8012, M8013, M8015, M8021, M8022, M8023, M8025, M7011, M7012, M7021, M7023)
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 17, 2025
Received: January 17, 2025

Dear Riley Chen:

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,

YAN FU -S
Digitally signed by YAN FU -S
Date: 2025.03.19 12:42:24 -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K250131

Device Name
IPL Hair Removal Device (M8011, M8012, M8013, M8015, M8021, M8022, M8023, M8025, M7011, M7012, M7021, M7023)

Indications for Use *(Describe)*
IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair.

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 #K250131

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

I. Submitter

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Date of preparation: 2025-01-13

II. Device

Name of Device: IPL Hair Removal Device
Model(s): M8011, M8012, M8013, M8015, M8021, M8022, M8023, M8025, M7011, M7012, M7021, M7023
Common or Usual Name: Light Based Over-The-Counter Hair Removal
Regulation 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

Predicate Device	Manufacturer	510(k) Number	Product code
Hair Removal Device (R2815-G Pro, R2815-G)	Shenzhen Jianchao Intelligent Technology Co., Ltd.	K232575	OHT
Intense Pulsed Light (IPL) System	Shenzhen Fansizhe Science and Technology Co., Ltd	K223928	OHT

IV. Device Description

IPL Hair Removal Device is an over-the-counter, home use, light based device for unwanted hair reduction by using Intense Pulsed Light (IPL) technology. The device works below the skin's surface and does not involve any cutting or pulling, removing hair growth with minimal pain.

The device includes 12 models, they are M8011, M8012, M8013, M8015, M8021, M8022, M8023, M8025, M7011, M7012, M7021, M7023. Those models with model name of "M80XX" are equipped

with cooling function for a better hair remove experience, while those of "M70XX" have no cooling function.

The device is only powered by the external power adapter and its IPL emission activation is by a switch or auto light emission, and it contains a skin sensor to detect appropriate skin contact, if the light outlet is not in full contact with the skin, the device cannot emit light pulses.

V. Indications for Use

IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair.

Comparison of Indications for Use: The indications for use of the subject device is comparable to the indications for use of the predicate devices.

VI. Comparison of Technological Characteristics With the Predicate Device

The IPL Hair Removal Device has the same indications for 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 no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate devices for its intended use. Therefore, the IPL Hair Removal Device may be found substantially equivalent to its predicate devices.
IPL Hair Removal Device is compared with the following predicate devices in terms of intended use, design, specifications and performance:

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Remark**
510(k) Number	Pending	K232575	K223928	/
Trade name	IPL Hair Removal Device	Hair Removal Device	Intense Pulsed Light (IPL) System	/
Model	M8011, M8012, M8013, M8015, M8021, M8022, M8023, M8025, M7011, M7012, M7021, M7023	R2815-G Pro, R2815-G	T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K	/
Indication for use/ Intended use	IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair.	Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair.	The Intense Pulsed Light (IPL) System is an over-the-counter device intended for the removal of unwanted body hair.	Same
Prescription or OTC	OTC	OTC	OTC	Same
Design	Hand-held	Hand-held	Hand-held	Same

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Remark**
Power source	An external power adapter	An external power supply	An external power supply	Same
Power supply	100-240V, 50/60Hz	100~240V, 50/60Hz	/	Same
Dimensions	M7011, M7012, M8011, M8012, M8013, M8015: 179mm x 65mm x 39mm M7021, M7023, M8021, M8022, M8023, M8025: 180mm x 71mm x 39mm	194*117*45mm	90*44*225mm for T016K	Different
Sterilization	Not required	Not required	Not required	Same
Light source	Intense Pulsed Light (IPL)	Intense Pulsed Light (IPL)	Intense Pulsed Light (IPL)	Same
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelength range	530nm-1200nm	530-1200nm	510nm~1200nm	Same
Energy density	M8011, M8012, M8013, M8015, M8021, M8022, M8023, M8025: **1.8~4.0J/cm²** M7011, M7012, M7021, M7023: **2.1~4.5J/cm²**	Max. 5.2J/cm^2 (range in 1.2J/cm^2~5.2J/cm^2)	Max. 5.73J/cm^2 for T016K	Similar
Output energy	M8011, M8012, M8013, M8015, M8021, M8022, M8023, M8025: **6.0~13.5J** M7011, M7012, M7021, M7023: **7.0~15.0J**	5~14.5J	4.8J~18.9J for T016K	Similar
Spot size	M8011, M8012, M8013, M8015, M8021, M8022, M8023, M8025: **3.4 cm²** M7011, M7012, M7021, M7023: **3.3cm^2**	3.4±0.25 cm²	3.3cm^2 for T016K	Same
Pulse duration	8.2~11.0ms	8.5±2.5ms (range in 6ms~11ms)	4 ~ 12ms	Similar
Pulsing control	Finger switch	Finger switch	Finger switch	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Same

Comparison Elements	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
Material of Patient contact components	ABS+PC, Sapphire (Al_2O_3), Reflective cover bracket (POM), Silicone stopper (Silica gel)	PC+ABS, Sapphire (Al_2O_3), Stainless steel 430	T016K: PC for button, PC for main housing and Probe cover, Sapphire Crystal Cooling Compress	Different, but solved by biocompatibility tests

VII. Non-Clinical Testing

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

- ISO 10993-5: 2009, Biological evaluation of medical devices –Par t 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation
- IEC 60601-1:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility
- IEC 60601-1-11:2020, 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 60601-2-83: 2022, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62471: 2006, Photobiological safety of lamps and lamp systems
- IEC 60601-1-6: 2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

VIII. Clinical Testing

Not applicable.

IX. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.