



September 15, 2025

Miley Technology (Hebei) Co., Ltd.
% Caixia Sun
Official Correspondent
Shenzhen Reanny Medical Devices Management Consulting Co.Ltd
Room 1509, Jingting Building,Dongzhou Community
Guangming Street,Guangming District
Shenzhen, Guangdong 518107
China

Re: K251914

Trade/Device Name: IPL Hair Removal Device (MLY-M011); IPL Hair Removal Device (MLY-M012); IPL Hair Removal Device (MLY-M013); IPL Hair Removal Device (MLY-M015); IPL Hair Removal Device (MLY-T001); IPL Hair Removal Device (MLY-T002)

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 30, 2025

Received: June 23, 2025

Dear Caixia Sun:

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](https://www.fda.gov/training-and-continuing-education/cdrh-learn)) 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,

Digitally signed by YAN
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Date: 2025.09.15 10:25:46
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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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251914

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Please provide the device trade name(s).

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IPL Hair Removal Device (MLY-M011);
IPL Hair Removal Device (MLY-M012);
IPL Hair Removal Device (MLY-M013);
IPL Hair Removal Device (MLY-M015);
IPL Hair Removal Device (MLY-T001);
IPL Hair Removal Device (MLY-T002)

Please provide your Indications for Use below.

?

IPL Hair Removal Device is an over-the counter device intended for removal of unwanted body hair. The device is used for adults with Fitzpatrick skin types I-IV.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

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K251914

510(k) Summary

Type of 510(k) submission:Traditional

Date prepared: September 11, 2025

Submitter's information

Submitter	Miley Technology (Hebei) Co.,Ltd.
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Applicant Correspondent

Company	Shenzhen Reanny Medical Devices Management Consulting Co.,Ltd.
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Contact person	Caixia Sun
Email	reanny@reanny.com
Tel	030-5600133

Device Identification

Trade Name	IPL Hair Removal Device
Model(s)	MLY-M011,MLY-M012,MLY-M013,MLY-M015,MLY-T001,MLY-T002
Regulation Number	21 CFR 878.4810
Classification Name	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Device Classification	Class II
Panel	General and Plastic Surgery
Product Code	OHT
Previous Submissions	None

Predicate Device information

Primary predicate device

Sponsor	Shenzhen Qianyu Technology Co.,Ltd.
Trade/Device Name	IPL Hair Removal Device,Model(s):JP1,JR3,JR8,JR9
510(k) Number	K231800
Regulation Number	21 CFR 878.4810

Secondary predicate device

Sponsor	Shenzhen Greatro Electronic Technology Co.,Ltd
Trade/Device Name	Intense Pulse Light Therapeutic Apparatus
510(k) Number	K242595
Regulation Number	21 CFR 878.4810

Indication for use

IPL Hair Removal Device is an over-the counter device intended for removal of unwanted body hair. The device is used for adults with Fitzpatrick skin types I-IV.

Device Description

IPL Hair Removal Device is a small over-the-counter device for the permanent reduction of hair growth based on Intense Pulsed Light (IPL). It works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain. The IPL Hair Removal Device includes main unit, an adaptor and goggles. The device is only powered by the external power adapter and its IPL emission activation is by a finger switch or auto light emission. If the light outlet of the device is not fully contact with the skin, the device cannot emit the treatment light pulses.

The device includes MLY-M011,MLY-M012,MLY-M013,MLY-M015,MLY-T001,MLY-T002 six models. There is difference in product appearance, cooling function, physical product dimension, indicator display and spot size, but their intended use, performance,output energy, structure design and operation are basically identical. MLY-M011 has no cooling function,while other models(MLY-M012,MLY-M013,MLY-M015,MLY-T001,MLY-T002) have cooling function.

Comparison of Technological Characteristics With the Predicate Devices

The IPL 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 no raise any issues of safety or effectiveness. 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.

Basic technological characteristics. New device VS Predicate devices

Device	Subject device	Predicate device 1	Predicate device 2	Comparison
Manufacturer	Miley Technology (Hebei) Co.,Ltd.	Shenzhen Qianyu Technology Co.,Ltd.	Shenzhen Greatro Electronic Technology Co.,Ltd	N/A
510(K) number	Pending	K231800	K242595	N/A
Product name	IPL Hair Removal Device(MLY-M011,MLY-M012,MLY-M013,MLY-M015,MLY-T001,MLY-T002)	IPL Hair Removal Device,Model(s):JP1,JR3,JR8 ,JR9	Intense Pulse Light Therapeutic Apparatus	N/A
Models	MLY-M011, MLY-M012, MLY-M013, MLY-M015, MLY-T001, MLY-T002	JP1, JR3, JR8, JR9	IPL-18 BF, IPL-18FG	N/A
Classification	Class II Device, OHT(21 CFR878.4810)	Class II Device, OHT (21 CFR878.4810)	Class II Device, OHT (21 CFR878.4810)	Same
Indications for Use (IFU)	IPL Hair Removal Device is an over-the counter device intended for removal of	IPL Hair Removal Device is an over-the counter device intended for removal of	Intense Pulse Light Therapeutic Apparatus is an over-the-counter device	Same The Fitzpatrick skin types of predicate device can refer to its

Device	Subject device	Predicate device 1	Predicate device 2	Comparison
	unwanted body hair. The device is used for adults with Fitzpatrick skin types I-IV.	unwanted body and/or facial hair.	intended for removal of unwanted body hair.	user manual. Note 1
OTC or Rx	OTC	OTC	OTC	Same
Classification Product Code	OHT	OHT	OHT	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc Flashlamp	Xenon Flashlamp	Xenon Arc lamp	Same
Source energy	Supplied by external adapter	Supplied by external adapter	Supplied by external adapter	Same
Power source	Input: AC100-240V ~ 50/60Hz, 1A. Output: DC12V $\overline{\text{---}}$ 3A	Input: AC100-240V ~ 50/60Hz, 1.5A Max.	Input: AC100-240V~ 50/60Hz Output: DC12V $\overline{\text{---}}$ 3A	Minor different Note 2
Irradiation area	MLY-M011: 2.5cm ² MLY-M012:3.0cm ² MLY-M015:3.0cm ² MLY-T001,;3.0cm ² MLY-T002: 3.0cm ² MLY-M013: 3.5cm ²	JP1: 1.6cm ² JR3: 3cm ² JR8&JR9: 3.42cm ² ±0.2cm ²	IPL-18BF:(3.5±0.25)cm ² IPL-18FG:(2.9±0.25)cm ²	Minor different Note 3
Wavelength	530~1200nm	JP1 & JR3: 590-1200nm JR8 & JR9: 560-1200nm	510~1200nm	Minor different Note 3

Device	Subject device	Predicate device 1	Predicate device 2	Comparison
Energy density/Fluence	1.6-3.5J/cm ²	JP1: 1.4~2.5J/cm ² JR3: 2.0~4.6J/cm ² JR8: 1.77~5.22J/cm ² JR9: 1.77~5.59J/cm ²	IPL-18 BF: 1.28~4.80J/cm ² IPL-18 FG:1.52~5.89J/cm ²	Minor different Note 3
Output energy	5-10J	Approximately 2.2-19.1J	Level 1: 6.0±1.2J Level 2: 7.5±1.5J Level 3: 9.5±1.9J Level 4: 11.0±2.2J Level 5: 13.0±2.6J Error is±20%	Different Note 3
Output intensity level	5 levels	JP1: 3 levels JR3: 6 levels JR8: 6 levels JR9: 5 levels	5 levels	Similar. The intensity level of subject device is same to the predicate device 2 and JR9 of predicate device 1 Note 3
Pulse duration	8±2.0ms	JP1 & JR3: 7.5ms±2ms JR8 & JR9: 8.2±2ms	10.0±3.0ms	Minor different Note 3

Device	Subject device	Predicate device 1	Predicate device 2	Comparison
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
Dimension	MLY-M011:130*67*38mm MLY-M012:180*66*39mm MLY-M013:170*58*30mm MLY-M015:178*68*38mm MLY-T001:175*60*42mm MLY-T002:178*65*37mm	JP1:188.15*58*70.6mm JR3:159*58**58mm JR8:158.6*58*39mm JR9:163.8*78.2*44.6mm	IPL-18 BF:154*79*46mm IPL-18 FG: 154*79*46mm	Different Note 4
Weight	MLY-M011:190g MLY-M012:258g MLY-M013:258g MLY-M015:258g MLY-T001:245g MLY-T002:244g	JP1&JR3:265g JR8:256g JR9:260g	IPL-18 BF:213g IPL-18 FG:201g	Different Note 4
Sterilization	Not required	Not required	Not required	Same

Device	Subject device	Predicate device 1	Predicate device 2	Comparison
Operating environment	Temperature: 10-30°C Relative humidity: 15-85%, without condensation Atmospheric Pressure:70 kPa to 106 kPa	Unknown	Temperature:5°C~30°C Humidity:≤80%RH	Minor different Note 5
Storage and transportation environment	Temperature: -20-55°C Relative humidity: 15-85%, without condensation Atmospheric Pressure:70 kPa to 106 kPa	Unknown	Temperature:-10~60°C Humidity:5%~90%	Minor different Note 5
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 ISO 10993-5 ISO 10993-10 ISO 10993-23	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 ISO 10993-5 ISO 10993-10 ISO 10993-23	Minor different. The standards of subject device are as same as predicate device 2 Note 6

Comparison discussion

Note 1:

The type of use of the subject device is same to the predicate device. The applicable skin of the subject device is Fitzpatrick Skin Type I-IV, which is different from predicate device 2,K242595(Fitzpatrick Skin Type I-V). However, the applicable skin of subject device is in the range of predicate device 2. Therefore, we consider the subject device with a broader scope of use environment and smaller range of applicable skin does not effect its safety and effectiveness.

Note 2:

The output of power source are different in current among the devices. The subject device and predicate device are supplied by an external power, they are both complied with IEC 60601-1, IEC 60601-1-2 and IEC60601-1-11, the safety and effectiveness of the subject device is verified via tests, so the differences do not affect the safety and effectiveness.

Note 3:

From the comparison table above, the device design between the predicate devices and subject device are mainly equivalent, the specifications of subject device are not completely same.The wavelength, irradiation area, energy density,output energy, output intensity level, pulse duration are similar or within the range of predicate devices. The key parameter for the safety and effectiveness of the hair removal device is energy density.The energy density of the subject device is in the range of that of the predicate devices. The safety and effectiveness of the subject device is verified via tests according to IEC 60601-1,IEC 60601-1-2, IEC 60601-1-11, IEC 62471 and IEC 60601-2-83, so the differences do not affect the safety and effectiveness.

Note 4:

The "Weight", "Dimension", are belonging to basic physical characteristics. Although it is a bit different from the predicate devices, it will not affect the main function and the intended use of the device. They all also comply with IEC60601-1 requirements. Besides, the subtle change of the physical characteristics will not affect the critical functions or normal use, and not raise any safety or effectiveness issues

Note 5:

The "Operating environment" and "Transportation & Storage environment" of subject devices may be differ from the predicate devices, but they are both compliance with the IEC 60601-1 and IEC 60601-1-11 standards, so the difference will not raise any safety or effectiveness Issue.

Note 6:

The "standards" of subject devices is same with predicate device 2 but minor different to the predicate device 1. The subject device is tested according to IEC 60601-2-83, this part of IEC 60601 has been prepared to provide safety requirements for HOME LIGHT THERAPY EQUIPMENT, based on IEC 60601-1 and its collateral standards. the subject is intended to be used in the HOME HEALTHCARE ENVIRONMENT and is typically used by a LAY OPERATOR, who is familiar with this environment and the

specific characteristics of lamps. Some requirements of IEC 60601-1-11 are amended to better suit this type of ME EQUIPMENT and the environment in which it is used. IEC 60601-2-83 is developed because IEC 60601-2-57 only covers light source equipment providing light therapy by means of non-visual photobiological effects, which excludes an important group of light source equipment creating visual photobiological effects. Further, IEC 60601-2-57 focuses on radiation aspects and related markings but hardly provides any product-specific safety requirements. IEC 60601-2-83 is aligned with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013, and IEC 60601-1-11:2015. Therefore, this difference will not raise any safety or effectiveness issue.

Performance data

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

The device meets all the applicable standards of :

- IEC 60601-1-11:2015+A1:2020 Medical electrical equipment - Part 1-11: 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 60601-1-2:2020 Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility
- IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-83:2019+A1:2022 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
- ISO 10993-5: 2009 Biological Evaluation of Medical Device - Part 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

Conclusions

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