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

Re: K241106
Trade/Device Name: Ice Cooling IPL Home Use Hair Removal Device (Model(s): T10B, T10C, 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: April 22, 2024
Received: April 22, 2024

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 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,

Yan Fu -S

Digitally signed by Yan Fu -S
Date: 2024.05.22 13:31:27 -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241106

Device Name
Ice Cooling IPL Home Use Hair Removal; Device Model(s): T10B, T10C, T15A, T17A, T18A, T14A, T16A, T19A

Indications for Use *(Describe)*
The Ice Cooling IPL Home Use Hair Removal Device is an over-the-counter device indicated for the 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.
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.

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510(k) Summary - K241106
"510(k) Summary" as required by 21 CFR Part 807.92.

1. Submitter Information

Shenzhen Mlay Intelligent Technology Co., Ltd.
302,401, Building 1, No. 2, Xiashiwei Road, Huaide Community, Fuyong Street, Baoan District, Shenzhen, Guangdong, China

Post Code: 518000

LIU LIBIN
General Manager
Tel.: +86 150 6071 0113
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2. Device Information

Trade name:	Ice Cooling IPL Home Use Hair Removal Device
Model(s):	T10B, T10C, 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:	Special 510(k)

3. Predicate Device

Primary predicate device:

Manufacturer	Predicate Device	510k Number	Decision Date
Shenzhen Mlay Intelligent Technology Co., Ltd	Home Use Hair Removal Device (Model(s):T10A, T10B, T10C, T10D, T11A, T15A, T17A, T18A, T14A, T16A, T19A)	K240264	March 8, 2024

Predicate device:

Manufacturer	Predicate Device	510k Number	Decision Date
Shenzhen Ulike Smart Electronics Co.,Ltd	IPL Hair Removal Device	K223618	Feb. 28, 2023
Shenzhen Ulike Smart Electronics	IPL Hair Removal Device	K221002	June 01, 2022

Co.,Ltd			
Shen Zhen CosBeauty Co., Ltd	IPL Hair Removal Device Joy Version	K173813	Sept. 07, 2018

4. Device Description

The Ice Cooling IPL 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 and it has the cooling function that effectively cools the skin.

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. Besides, the device has the cooling function that will be activated throughout the whole hair removal process or when the user want to activated to provide users with a more comfortable experience.

5. **Indications for Use**

The Ice Cooling IPL Home Use Hair Removal Device is an over-the-counter device indicated for the 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. 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.

6. **Comparison of Technological Characteristics With the Predicate Device**

The Ice Cooling IPL Home Use Hair Removal Device has the same intended use, mode of action and operational characteristics as the models T10B, T10C, T15A, T17A, T18A, T14A, T16A, T19 in the predicate devices. The modification 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 primary predicate device and predicate device for its intended use. Therefore, the Ice Cooling IPL Home Use Hair Removal Device may be found substantially equivalent to its predicate device.

Ice Cooling IPL Home Use Hair Removal Device is compared with the primary predicate device and predicate device as belows:

Comparison Elements	Subject Device	Primary Predicate Device K240264	Comparison
K Number	Pending	K240264	/
Trade name	Ice Cooling IPL Home Use Hair Removal Device, Model(s): T10B, T10C, T15A, T17A, T18A, T14A, T16A, T19A	Home use hair removal device, Model(s): T10A, T10B, T10C, T10D, T11A, T15A, T17A, T18A, T14A, T16A, T19A	Similar Note[1]
Location for use	OTC	OTC	SE
Indications for Use	The Ice Cooling IPL Home Use Hair Removal Device is an over-the-counter device indicated for the 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. 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.	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.	Similar Note[2]
Ice cooling function	Model(s): T10B, T10C, T15A, T17A, T18A, T14A, T16A, T19A have cooling function	(1)Model(s): T10A, T10D, T11A do not have cooling function. (2)Model(s): T10B, T10C, T15A, T17A, T18A, T14A, T16A, T19A have cooling function	SE Note[3]
Cooling panel's material	T10B, T10C: artificial sapphire T15A, T17A, T18A, T14A, T16A, T19A: 5052 aluminum alloy	T10A,T10D,T 11A :have not cooling function T10B, T10C: artificial sapphire T15A, T17A, T18A, T14A, T16A, T19A: 5052 aluminum alloy	
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	SE
Light Source	Intense Pulsed Light	Intense Pulsed Light	SE
Pulsing control	Finger switch	Finger switch	SE
Delivery device	Direct illumination tissue	Direct illumination tissue	SE
Energy density	T10B, T10C, T15A, T17A, T18A: 1.37 ~ 4.11J/cm^2 T14A,T16A, T19A: 1.84 ~ 5.23J/cm^2	T10A, T10B, T10C, T10D, T11A, T15A, T17A, T18A: 1.37 ~ 4.11J/cm^2 T14A,T16A, T19A: 1.84 ~ 5.23J/cm^2	SE

Comparison Elements	Subject Device	Primary Predicate Device K240264	Comparison
K Number	Pending	K240264	/
Treatment energy level	(1)Model(s)T17A,T18A:have 3 levels; Level 1 to Level 3 (2)Model(s)T10B, T10C, T15A, T14A, T16A, T19A: have 5 levels; Level 1 to Level 5	(1)Model(s)T11A,T17A,T18A:have 3 levels; Level 1 to Level 3 (2)Model(s)T10A, T10B, T10C, T10D, T15A, T14A, T16A, T19A: have 5 levels; Level 1 to Level 5	SE Note[3]
Spot size	T10B,T10C, T15A, T17A, T18A: 3.5cm^2 T14A,T16A, T19A: 3.9cm^2	T10A, T10B, T10C, T10D, T11A, T15A, T17A, T18A: 3.5cm^2 T14A,T16A, T19A: 3.9cm^2	SE
Pulse duration	T10B, T10C,T15A, T17A, T18A: 4.0~8.0ms T14A,T16A, T19A: 0.5~2.5ms	T10A, T10B, T10C, T10D, T11A, T15A, T17A, T18A: 4.0~8.0ms T14A,T16A, T19A: 0.5~2.5ms	SE
Pulse interval	T10B, T10C：0.5~2.8s T15A, T17A, T18A: 0.7~2.5s T14A,T16A, T19A: 0.5~1.5s	T10A, T10B, T10C, T10D：0.5~2.8s T11A：1.0~2.5s T15A, T17A, T18A: 0.7~2.5s T14A,T16A, T19A: 0.5~1.5s	SE
Treatment window to be designed as removable or non-removable	(1)Model(s) T10B, T10C,T15A, T17A, T18A:non-removable (2)Model(s)T14A,T16A,T19A:removable	(1)Model(s)T10A, T10B, T10C, T10D, T11A,T15A,T17A, T18A:non-removable (2)Model(s)T14A,T16A,T19A:removable	SE Note[3]
Design Software Features Materials Energy source Principle of operation	The models applied for this time are exactly the same as these models T10B, T10C, T15A, T17A, T18A, T14A, T16A, T19A in K240264.		SE

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
K Number	Pending	K223618	K221002	K173813	/
Trade name	Ice Cooling IPL Home Use Hair Removal Device, Model(s): T10B, T10C, T15A, T17A, T18A, T14A, T16A, T19A	IPL Hair Removal Device	IPL Hair Removal Device (UI04A, UI04B, UI04C)	IPL Hair Removal Device Joy Version, CB- 027	Similar Note[1]
Location for use	OTC	OTC	OTC	OTC	SE
Indications for Use	The Ice Cooling IPL Home Use Hair Removal Device is an over-the-counter device indicated for the 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. 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	IPL Hair Removal Device is 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 number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	IPL Hair Removal Device is 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 number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	The IPL Hair Removal Device Joy Version is 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 number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. The device is used for adults with Fitzpatrick skin types I - IV.	Similar Note[2]

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
K Number	Pending	K223618	K221002	K173813	/
	after the completion of a treatment regime.				
Applicable skin	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Fitzpatrick skin types I - IV	Similar
Treatment area	Large areas(e.g. legs) and small areas(e.g.underarm, facial hair below the chin line)	Large areas (e.g. arms, legs, chest) and small areas (e.g. lip)	Large areas (e.g.arms, legs, chest) and small areas (e.g. fingers, lip)	Large areas (legs, arms, back and abdomen), face (upper lip, chin and sideburns)	Similar
Output specification					
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	SE
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	SE
Wavelength range	510~1200nm	560~1200nm	550~1200nm	510~1200nm	Similar Note[4]
Energy density	T10B, T10C, T15A, T17A, T18A: 1.37 ~ 4.11J/cm^2 T14A,T16A, T19A: 1.84 ~ 5.23J/cm^2	3~6J/cm^2	3.03~5.3J/cm^2	1.8~5.1J/cm^2	Similar Note[5]

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3		Comparison
K Number	Pending	K223618	K221002	K173813		/
Output energy	T10B, T10C, T15A, 17A,T18A: 6~12J T14A, T16A, T19A: 9~ 17J	9.9~19.8J	10.0~17.5J	Body lamp cartridge	11.77~22.21J 510~1200nm	Similar Note[5]
				Facial lamp cartridge	3.65~7.04J 512~1197nm	
				Bikini lamp cartridge	3.84~7.22J 511~1200nm	
Spot size	T10B, T10C, T15A, 17A,T18A: 3.5cm^2 T14A, T16A, T19A: 3.9cm^2	3.3cm^2	3.3cm^2	Body: 4.2cm^2 Bikini and face: 2.0cm^2		Similar Note[6]
Pulse duration	T10B, T10C, T15A, 17A,T18A: 4.0~8.0ms T14A, T16A, T19A: 0.5~2.5ms	1~7ms	7~10ms	9.2~11.2ms		Similar Note[7]
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch		SE
Delivery device	Direct illumination tissue	Direct illumination tissue	Direct illumination tissue	Direct illumination tissue		SE

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
K Number	Pending	K223618	K221002	K173813	/
Output intensity level	T17A,T18A: 3 levels T10B, T10C, T15A, T14A, T16A, T19A: 5 levels	3 levels	5 levels	5 levels	Similar
Software/ Firmware/ Microprocess or Control	Yes	Yes	Yes	Yes	SE
Additional features					
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	IEC 60601-1-2 IEC 60601-1-11 ANSI AAMI ES60601-1 IEC 60601-2-57 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	Similar

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Comparison
K Number	Pending	K223618	K221002	K173813	/
Eye safety	IEC62471	IEC 62471	IEC 62471	IEC 62471	SE
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-12	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Similar

Note[1]: These model(s): T10B, T10C, T15A, T17A, T18A, T14A, T16A, T19A all provide hair reduction using Intense Pulsed Light technology and it has the cooling function that effectively cools the skin, so the device name changes from “Home use hair removal device” to “Ice Cooling IPL Home Use Hair Removal Device”. The user can get the information about the function of the device by the device name, which is convenient for the user to self-select for the device.

Note[2]:The Indications for Use descriptions of the subject device and the predicate device are essentially the same, except that the wording is different. 1) The user manual and the outer packaging label specify the hair colors that the device can be used to treat, so the words "in patients with Fitzpatrick Skin Phototypes I-V" have been deleted. 2) In order to allow the user to clearly understand the results they can achieve if they use the device for a long term, the following words have been added: "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.". The technical parameters of the subject device are similar to those of the predicate device. The results of the comparison show that the subject device can achieve this result.

Note[3]:The same models are totally same.

Note[4]:Though the wavelength of subject device is a little different from the predicate device, they all comply with IEC 60601-2-57/IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Note[5]:Though the energy density and the output energy of subject device is a little different from the predicate devices, the energy density and the output energy of subject device is within the range of the maximum value of the predicate devices, and they all comply with IEC 60601-2-57/IEC 60601-2-83 and IEC 62471 requirement, so this difference will not raise any safety or effectiveness issue.

Note[6]:There is minor difference in spot size between the subject device and the predicate devices. The spot size is related to energy density and since the difference in energy density is not significant as explained in note[5], so this difference will not raise any safety or effectiveness issue.

Note[7]:Though the pulse duration of subject device is a little different from the predicate device, it’s basically within the range of the predicate devices, and the subject device comply with IEC 60601-2-57/IEC 60601-2-83 and IEC 62471 requirement, so this difference will not raise any safety or effectiveness issue.

7. Non-clinical studies and tests performed

Non-clinical tests have been conducted to verify that the Ice Cooling IPL Home Use Hair Removal Device meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate devices. The testing results demonstrate that the subject device conforms to the following performance standards:

- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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
- IEC 60601-1-6, 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 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 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
- IEC 62471, Photobiological safety of lamps and lamp systems
- IEC 62366-1, Medical devices Part 1: Application of usability engineering to medical devices

The device has been tested for biocompatibility for conformance to the following performance standards:

- ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro 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

Software Verification and Validation

Software verification and validation was performed, and it was demonstrated that the software performs as intended according to the FDA Guidance for the Content of Premarket Submissions for Device Software Functions.

8. Conclusion

Based on the above analysis, it can be concluded that the subject device Ice Cooling IPL Home Use Hair Removal Device meets the product requirements, which is based on the primary predicate device， and substantially equivalent to these predicate devices for permanent reduction in hair regrowth. Therefore, the modification resulted in a device that performs within the same specifications of the primary predicate device and the predicate devices, and is therefore substantially equivalent.