August 14, 2025

Shenzhen Mlay Intelligent Technology Co., Ltd.
Libin Liu
General Manager
201, 301, Building 28, Cuigang Industrial Zone 2, Huaide
Community, Fuyong Street, Baoan District, Shenzhen City,
Shenzhen, 518103
China

Re: K251176
Trade/Device Name: IPL Hair Removal Device (Model(s): T14B, T16B, T19B, T15B, T17C, T18B, T21A, T21B, T21C, T21D, T22A, T22B, T25B, T25C)
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 15, 2025
Received: April 16, 2025

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.

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.08.14 15:36:15 -04'00'

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)*
K251176

Device Name
IPL Hair Removal Device (Model(s): T14B, T16B, T19B, T15B, T17C, T18B, T21A, T21B, T21C, T21D, T22A, T22B, T25B, T25C)

Indications for Use *(Describe)*
The IPL 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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K251176 - 510(k) Summary

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

1. Submitter Information

Shenzhen Mlay Intelligent Technology Co., Ltd.
201, 301, Building 28, Cuigang Industrial Zone 2, Huaide Community, Fuyong Street, Baoan District, Shenzhen City, Guangdong Province, China.
Post Code: 518103
LIU LIBIN
General Manager
Tel.: +86 18344147065
Email: wuxiaotian@mlays.com
Date Prepared: August 8, 2025

2. Device Information

Trade name:	IPL Hair Removal Device
Model(s):	T14B, T16B, T19B, T15B, T17C, T18B, T21A, T21B, T21C, T21D, T22A, T22B, T25B, T25C
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 Mlay Intelligent Technology Co., Ltd.	Ice Cooling IPL Home Use Hair Removal Device (Model(s):T10B, T10C, T15A, T17A, T18A, T14A, T16A, T19A)	K241106	April 22, 2024
Shenzhen Fansizhe Science and Technology Co., Ltd.	Intense Pulsed Light (IPL) System, model: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K	K223928	March 28, 2023
Shenzhen Ulike Smart Electronics Co., Ltd.	Ice Cooling IPL Hair Removal Device	K242039	October 25, 2024
Shenzhen Ulike	IPL Hair Removal Device	K230122	January 17,

Smart Electronics Co., Ltd.			2023

4. Device Description

The IPL 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(suitable for model T21A, T21B and T22A, T22B). The device provides hair reduction using Intense Pulsed Light technology and cooling technology (suitable for model T14B, T16B, T19B, T15B, T17C, T18B, T21C, T21D, T25B, T25C).

The Intense Pulsed Light technology 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 Quartz glass 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; If the device is properly and fully applied to the skin of the treatment area, the device can emit light pulses in as quickly as 0.5 seconds. In automatic mode, it supports continuous flashing and automatic light emission.

In auto-recognition skin color mode, the skin tone sensor can detect and identify the color of skin, and determine the required intensity based on the recognized skin color. Make sure the skin tone sensor is in full contact with the skin. If a valid skin color is detected, the corresponding energy level is displayed. If it is not in full contact with the skin, the energy level is 0 and no light pulses are emitted.

The cooling technology based on the temperature difference electrical phenomenon through the semiconductor cooling chip inside the IPL main device and uses the principle of the Peltier effect to achieve the purpose of cooling function. The cooling panel is located around the light-emitting window (suitable for model T14B, T16B, T19B) and does not affect the irradiated area (spot size) of the light outlet; The cooling panel is constructed with sapphire, (suitable for model T15B, T17C, T18B, T21C, T21D, T25B, T25CB) and does not affect the irradiated area (spot size) of the light outlet.

The device is available in two designs: straight-panel and gun-shaped, both featuring a compact and lightweight form factor. Moreover, The enterprise has reserved an ample quantity of lamp heads to ensure maintenance accessibility and end-user convenience.

5. Indications for Use

The IPL 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 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 efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use. Therefore, the IPL Hair Removal Device may be found substantially equivalent to its predicate device.

The IPL 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 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Comparison
K Number	Pending	K241106	K223928	K242039	K230122	/
Trade name	IPL Hair Removal Device, Model(s): T14B, T16B, T19B, T15B, T17C, T18B, T21A, T21B, T21C, T21D, T22A, T22B, T25B, T25C	Ice Cooling IPL Home Use Hair Removal; Device Model(s): T10B, T10C, T15A, T17A, T18A, T14A, T16A, T19A	Intense Pulsed Light (IPL) System, model: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K	Ice Cooling IPL Hair Removal Device	IPL Hair Removal Device	/
Manufacturer	Shenzhen Mlay Intelligent Technology Co., Ltd.	Shenzhen Mlay Intelligent Technology Co., Ltd.	Shenzhen Fansizhe Science and Technology Co., Ltd	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen Ulike Smart Electronics Co.,Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT	OHT	OHT	OHT	OHT	Same
Device classification	Class II	Class II	Class II	Class II	Class II	Same
Location for use	OTC	OTC	OTC	OTC	OTC	Same

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Comparison
Applicable skin	Fitzpatrick Skin Phototypes I-V	Fitzpatrick Skin Phototypes I-V	Unknown	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Same
Treatment area	Small areas such as underarm and facial hair below the chin line and large areas such as legs.	Large areas(e.g. legs) and small areas(e.g.underarm, facial hair below the chin line)	Unknown	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. lip)	Same
Power source	An external power supply	An external power supply	an external power supply	Supplied by external adapter	Supplied by external adapter	Same
Power supply	T14B,T16B,T19B: AC 100-240V, 50/60Hz, 2.5A MAX T15B, T17C, T18B, T21A, T21B, T21C, T21D, T22A, T22B, T25B, T25C: AC 100-240V, 50/60Hz, 1.5A	T10B, T10C, T15A, T17A, T18A: 48W(12V 4A) T14A, T16A, T19A: input AC100-240V; 50/60Hz; 2.5A	Unknown	100-240V~, 50/60Hz	100-240V~, 50/60Hz	SE NOTE 1
Dimension	T14B:123.8*49.4*176.1mm T16B:122.0*46.8*175.0mm T19B:137.0*59.0*197	T10B: 186.8*59.7*42.0 mm T10C:186.8*59.7*42.0 mm T15A:	116*217.8*42mm for T023K, T023A, T023B, T023C, T023D and T023E, 73.2*81.1*202.2mm	206.73mm*68.68mm*54.29mm	60mm*38mm*170mm	SE NOTE 1

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Comparison
	.0mm T15B:163.0*66.0*43. 0mm T17C:169.5*80.1*52. 3mm T18B:171.0*65.2*45. 5mm T21A:153.6*82.5*50. 3mm T21B:153.6*82.5*50. 3mm T21C:153.6*82.5*50. 3mm T21D:153.6*82.5*50. 3mm T22A:135.8*84.6*49. 5mm T22B:135.8*84.6*49. 5mm T25B:164.0*63.5*41. 0mm T25C:164.0*63.5*41. 0mm	163.0*66.0*43.0 mm T17A: 169.5*80.1*52.3 mm T18A: 171.0*65.2*45.5 mm T14A: 123.8*49.4*176.1 mm T16A: 122.0*46.8*175.0 mm T19A: 137.0*59.0*197.0 mm	for T021K and T021A 182*78*151mm for T001A, T001B, T001M and T001N, 211*138*60mm for T011C, 90*44*225mm for T016K			
Sterilization	Not required	Not required	Not required	Not required	Not required	Same

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Comparison
Wavelength range	510~1200nm	510~1200nm	510~1200nm	550-1200mm	560-1200nm	SE NOTE 2
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Light Source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Finger switch	Same
Delivery device	Direct illumination tissue	Direct illumination tissue	Direct illumination tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Max. Fluence (J/cm^2)	5.90J/cm^2	5.23J/cm^2	5.75J/cm^2	6.41J/c m^2	7.2J/cm^2	SE NOTE 2
Spot size	3.1cm^2, 3.5cm^2, 3.9cm^2	3.5cm^2, 3.9cm^2	3.0cm^2, 3.3cm^2, 3.6cm^2, 4.0cm^2	3.9cm^2	3.3cm^2	SE NOTE 2
Pulse duration	0.4~5.5ms	0.5~8.0ms	4 ~ 12ms	0.93ms~3.50ms Single pulse Double pulse Triple pulse	1.15-6.2ms	SE NOTE 2
Software / Firmware Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Same
Availability of skin sensors (that used to identify the	Presence	Presence	Presence	Presence	Presence	Same

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Comparison
presence or absence of skin areas)						
Cooling function	Presence	Presence	Presence	Presence	Presence	Same
Skin pigmentation sensor	Detect appropriate skin tones	No	Detect appropriate skin tones	Detect appropriate skin tones	No	SE NOTE 3
Indication for use / intended use	The IPL 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,	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	The Intense Pulsed Light (IPL) System is an over - the - counter device intended for the removal of unwanted body hair.	Ice Cooling IPL Hair Removal Device with sapphire treatment window 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	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	Same

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Comparison
	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.	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.		number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	completion of a treatment regime.	
Electrical safety statement & EMC safety statement	IEC60601-1:2005+AMD1:2012+AMD2:2020 CVS IEC60601-1-6:2010+AMD1:2013+AMD2:2020 CSV IEC60601-1-11:2015+AMD1:2020 CVS IEC60601-1-2:2014/AMD1:2020 IEC TS 60601-4-2:2024	IEC60601-1:2005+AMD1:2012+AMD2:2020 CVS IEC60601-1-6:2010+AMD1:2013+AMD2:2020 CSV IEC60601-1-11:2015+AMD1:2020 CVS IEC60601-1-2:2014/AMD1:2020	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 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	SE NOTE 4
Photobiological statement	IEC60601-2-57:2011 IEC60601-2-83:2019+	IEC60601-2-57:2011 IEC60601-2-83:2019+	IEC 62471	IEC 62471	IEC 62471	SE NOTE 4

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Comparison
	AMD1:2022 CSV IEC62471:2006 & IEC62471:2008	AMD1:2022 CSV IEC62471:2006				
Materials statement	ISO10993-1:2018 ISO10993-5:2009 ISO10993-10:2021 ISO10993-23:2021	ISO10993-1:2018 ISO10993-5:2009 ISO10993-10:2021 ISO10993-23:2021	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	SE NOTE 4

Comparison in details:

NOTE 1: Although the "power supply", "Product appearance", "Dimensions", "Weight", "Environment for operation" and "Environment for storage" of subject device is a little different from the predicate devices, it will not affect the main function and the intended use of the subject device as 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.

NOTE 2: Although the "Wavelength range", "Spot size", "Energy density", and "pulse duration" of subject device is a little different from the predicate devices; they are very similar, and it will not affect the main function and the intended use of the subject device as they all also comply with IEC60601-1, IEC60601-1-6, IEC60601-11 requirements, so these parameters' differences will not raise any safety or effectiveness issue. Also, the "Wavelength range", "Spot size", "Energy density", and "pulse duration" of the subject device is different from the predicate, but its value is within the range of other predicate devices. so this parameter's difference will not raise any safety or effectiveness issue.

NOTE 3:Although there is a difference of the skin pigmentation sensor between the subject device and predicate device 1, but the predicate device 2 and 3 also have the skin pigmentation sensor to detect appropriate skin tones, so such difference would not raise safety or effectiveness issue.

NOTE 4: According to the FDA regulation classification and device characteristics, the subject device belongs to the OHT product code, the regulation recommends that such products comply with the IEC62471 standard requirements. In addition, the relevant tests shall be selected to prove the safety and effectiveness of the subject device according to its design characteristics and features. The battery of testing was performed to, and passed, including:

1) The subject device is powered by an external device and belongs to an active medical device, so the device needs to be tested for 'electrical safety and electromagnetic compatibility' in accordance with the requirements of the standard IEC60601-1 and IEC60601-1-2;

2) And the subject device belongs to a medical electrical equipment, so the device needs to be tested for the 'General requirements for basic safety and essential performance - Collateral standard: Usability' in accordance with the requirements of the standard IEC60601-1-6;

3) And the subject device belongs to a household medical device, so the device needs to be tested for 'the requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment' in accordance with the requirements of the standard IEC60601-1-11;

4) And the subject device is a household light source (non-laser) equipment, so the device needs to be tested for 'the particular requirements for the basic safety and essential performance of such devices' in accordance with the requirements of the standard IEC60601-2-57 and/or IEC60601-2-83.

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 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

2) Electrical Safety and EMC 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 60601-1-2:2014/AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC60601-1-6:2010/AMD1:2013/AMD2:2020 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 60601-2-57:2011 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 60601-2-83:2019/AMD1:2022 Medical Electrical Equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

3) Eye Safety

- IEC 62471:2006 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 IPL 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 IPL Hair Removal Device is to be concluded substantially equivalent to its predicate devices.