March 11, 2026

Shenzhen Chuangtong Yigou Technology Co., Ltd.
% Candice Qiu
Registration specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center
3101-90, Qianhai Rd.
Shenzhen, Guangdong 518052
China

Re: K254047
Trade/Device Name: Hair Removal Device (CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12 Pro, CTU05, CTU07, CTU09, CTU012, CTU015, CTU X, DT015 Pro, DT015, DT017 Pro, DT017, DT025 Pro, DT025)
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: December 1, 2025
Received: December 17, 2025

Dear Candice Qiu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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: 2026.03.11 23:34:00 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K254047.IFU Final

Device Name
Hair Removal Device (CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12 Pro, CTU05, CTU07, CTU09, CTU012, CTU015, CTU X, DT015 Pro, DT015, DT017 Pro, DT017, DT025 Pro, DT025)

Indications for Use *(Describe)*
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.

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 # K254047

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

Submitter
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Preparation Date: February 6, 2026

I. Device

Name of Device: Hair Removal Device

Model(s): CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12 Pro, CTU05, CTU07, CTU09, CTU012, CTU015, CTU X, DT015 Pro, DT015, DT017, DT017 Pro, DT025 Pro, DT025.

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

II. Predicate Device and reference device

- **For Model CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12 Pro**

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Chuangtong Yigou Technology Co., Ltd.	Hand-held Hair Removal Device (Model: FZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09)	K251000	July 01, 2025

reference device:

Manufacturer	reference device	510(k) Number	Approval Date
Shenzhen Siken 3D Technology Development Co., Ltd.	IPL Cooling Hair Removal Device (Model: SKB-1808)	K232845	November 14, 2023

- **For Model CTU05, CTU07, CTU09, CTU012 , CTU015, CTU X**

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Foshan Jindi Electric Appliance Co.,Ltd	IPL Home Use Hair Removal Device (Model: JD-TM027)	K252209	October 10, 2025

- **For Model DT015 Pro, DT015, DT017, DT017 Pro, DT025, DT025 Pro**

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Ulike Smart Electronics Co.,Ltd.	Ice Cooling IPL Hair Removal Device (Model: UI20S DB, UI20S RE, UI20S PW, UI20S GP, UI20S GR, UI20S BK, UI20 DB, UI20 RE, UI20 PW, UI20 GP, UI20 GR, UI20 BK)	K250942	Jully 11, 2025

IV. Device Description

Hair Removal Device, is an over-the-counter, home-use device for unwanted hair reduction by using Intense Pulsed Light (IPL), and it has been designed eighteen models with the same IPL technology for hair removal, which is model CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12 Pro, CTU05, CTU07, CTU09, CTU012, CTU015, CTU X, DT015 Pro, DT015, DT017, DT017 Pro, DT025 Pro, DT025. The device 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 Hair Removal Device has an irreplaceable light exit and it can cover an area of 3.0cm^2 (Model CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12 Pro, CTU05, CTU07, CTU09, CTU012 , CTU015, CTU X) and 4.2cm^2 (Model DT015 Pro, DT015, DT017, DT017 Pro, DT025, DT025 Pro) that is suitable for multiple hair removal areas, such as upper lip, chin, armpits, legs, arms, bikini area, chest, back, abdomen.

The device contains a skin sensor to detect appropriate skin contact, if the light exit is not in full contact with the skin, the device cannot emit the treatment light pulses. Besides, the Hair Removal Device has the Ice-cooling function (Model: CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12) and Sapphire Ice-cooling function (Model: CTU05, CTU07, CTU09, CTU012, CTU015, CTU X, DT015 Pro, DT015, DT017, DT017 Pro, DT025 Pro, DT025), which will be activated throughout the whole hair removal process to cool down the treatment area's temperature and provide the user with a better using experience.

V. Indications for Use

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.

VI. Materials

Model	Component name	Material of Component	Body Contact Category	Contact Duration
CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12 Pro	Host of device (including air outlet, treatment window, air inlet, buttons, filter)	AL-6063, PC+ABS AC2300, PC2805, Corning glass	Surface-contacting device: Intact skin	Less than 24 hours
CTU05, CTU07, CTU09, CTU012, CTU015, CTU X		PC+ABS AC2300, PC2805, ABS 15E1, Aluminium oxide, Corning glass		
DT015 Pro, DT015, DT017, DT017 Pro, DT025 Pro, DT025		PC+ ABS, PC, Aluminium oxide, Quartz glass		

VII.Comparison of Technological Characteristics With the Predicate Device

The 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 and reference 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 and reference device for its intended use. Therefore, the Hair Removal Device may be found substantially equivalent to its predicate device and reference device.

Hair Removal Device is compared with the following Predicate Device and reference device in terms of intended use, design, material, specifications, and performance:

- For CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12 Pro

Comparison Elements	Subject Device	Predicate Device	Reference Device	Remark
510(k) Number	Pending	K251000	K232845	/

Comparison Elements	Subject Device	Predicate Device	Reference Device	Remark
510(k) Number	Pending	K251000	K232845	/
Trade name	Hair Removal Device	Hand-held Hair Removal Device	IPL Cooling Hair Removal Device	/
Model	CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12 Pro	FZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09	SKB-1808	/
Manufacturer	Shenzhen Chuangtong Yigou Technology Co., Ltd.	Shenzhen Chuangtong Yigou Technology Co., Ltd.	Shenzhen Siken 3D Technology Development Co., Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT	OHT	OHT	Same
Device classification	Class II	Class II	Class II	Same
Indication for use/ Intended use	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.	Hand-held 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 Cooling Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair.	Same
Prescription or OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick Skin Types I-V	Fitzpatrick skin types I-V	Fitzpatrick Skin Types I-V	Same
Power supply	Input: AC 100-240V, 50/60 Hz, 0.8A Output: 24VDC, 1.5A	100-240V, 50/60Hz, 0.8AMax	Input: AC100~240V 50/60Hz Output: DC12V 4A	Same

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device**	**Remark**
510(k) Number	Pending	K251000	K232845	/
Dimension	201(W)x71(H)x52(L)mm	FZ-200A: 199*68*58(mm) FZ-201: 179*64*39mm FZ-202: 202*132*93mm CT05, CT06: 179*640*39(mm) CT07: 204*173*54(mm) CT08: 192*140*54(mm) CT09: 177*120*91(mm)	203*161*58mm	**Difference** **Note 1**
Sterilization	Not required	Not required	Not required	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp	Xenon Arc lamp	Xenon Arc Flashlamp	Same
Wavelength range	590nm-1200nm	590-1200nm	590-1200nm	Same
Energy density	2-4.4J/cm²	2-4.3 J/cm²	Max. 4.8J/cm² (range in 2.1~4.8J/cm²)	**Similar** **Note 2**
Output energy	6-13J(±20%)	6-13 J	8-12J	Same
Spot size	3.0cm²	3cm²	3cm²	Same
Pulse duration	8-15ms	2-6 ms	10±5ms	
Pulsing control	Finger switch	Finger switch	Finger switch	Same
Output intensity level	9 levels	9 levels	5 levels	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Same

Comparison Elements	Subject Device	Predicate Device	Reference Device	Remark
510(k) Number	Pending	K251000	K232845	/
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	Same
Eye safety	IEC 62471	IEC 62471	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

- For CTU05, CTU07, CTU09, CTU012 , CTU015, CTU X

Comparison Elements	Subject Device	Predicate Device	Remark
510(k) Number	Pending	K252209	/
Trade name	Hair Removal Device	IPL Home Use Hair Removal Device	/
Model	CTU05, CTU07, CTU09, CTU012 , CTU015, CTU X	JD-TM027	/
Manufacturer	Shenzhen Chuangtong Yigou Technology Co., Ltd.	Foshan Jindi Electric Appliance Co.,Ltd	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT	OHT	Same
Device classification	Class II	Class II	Same
Indication for use/ Intended use	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	IPL Home Use Hair Removal Device is an over-the counter device intended for removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth,	Same

Comparison Elements	Subject Device	Predicate Device	Remark
510(k) Number	Pending	K252209	/
	the completion of a treatment regime.	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.	
Prescription or OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Same
Power supply	100-240V, 50/60 Hz	100~240V, 50/60Hz	Same
Dimension	115(W)x69(H)x41(L)mm	182*60*35mm	**Difference Note 1**
Sterilization	Not required	Not required	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp	Xenon Arc flashlamp	Same
Wavelength range	560nm-1200nm	550-1200nm	**Similar Note 2**
Energy density	2.6-4.7J/cm²	2± 0.4~8± 1.6J/cm²	**Similar Note 3**
Output energy	8-14J(±20%)	6± 1.2~24 ±4.8J	**Similar Note 3**
Spot size	3.0cm²	3.0± 0.2cm²	Same
Pulse duration	1.52-8.32ms	0.2± 0.04ms~10ms± 2ms	**Similar Note 4**
Pulsing control	Finger switch	Finger switch	Same
Output intensity level	5 levels	5levels~9levels	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Same
Electrical safety	IEC 60601-1	IEC 60601-1	Same

Comparison Elements	Subject Device	Predicate Device	Remark
510(k) Number	Pending	K252209	/
	IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	
Eye safety	IEC 62471	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same

- For DT015 Pro, DT015, DT017, DT017 Pro, DT025, DT025 Pro

Comparison Elements	Subject Device	Predicate Device	Remark
510(k) Number	Pending	K250942	/
Trade name	Hair Removal Device	Ice Cooling IPL Hair Removal Device	/
Model	DT015 Pro, DT015, DT017, DT017 Pro, DT025, DT025 Pro	UI20S DB, UI20S RE, UI20S PW, UI20S GP, UI20S GR, UI20S BK, UI20 DB, UI20 RE, UI20 PW, UI20 GP, UI20 GR, UI20 BK	/
Manufacturer	Shenzhen Chuangtong Yigou Technology Co., Ltd.	Shenzhen Ulike Smart Electronics Co.,Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT	OHT	Same
Device classification	Class II	Class II	Same
Indication for use/ Intended use	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	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,	Same

Comparison Elements	Subject Device	Predicate Device	Remark
510(k) Number	Pending	K250942	/
	the completion of a treatment regime.	stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	
Prescription or OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Same
Power supply	100-240V, 50/60 Hz	100-240V~, 50/60Hz	Same
Dimension	198(W)x64(H)x40(L)mm	206.73mm*68.68mm*54.29mm	**Difference Note 1**
Sterilization	Not required	Not required	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp	Xenon Arc Flashlamp	Same
Wavelength range	560nm-1200nm	550-1200mm	**Similar Note 2**
Energy density	2.1-5J/cm²	1.65~6.92J/cm²	**Similar Note 3**
Output energy	9.1-21J(±20%)	4.29~27J	**Similar Note 3**
Spot size	4.2cm²	3.9cm²	**Similar Note 4**
Pulse duration	0.86-5.96ms quadruple pulse	0.86-6.32ms double pulse quadruple pulse	**Similar Note 5**
Pulsing control	Finger switch	Finger switch	Same

Comparison Elements	Subject Device	Predicate Device	Remark
510(k) Number	Pending	K250942	/
Output intensity level	5 levels	1-10 levels	**Difference Note 1**
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Same
Electrical safety	IEC 60601-1 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	Same
Eye safety	IEC 62471	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same

VIII. Performance Data

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

1) Biocompatibility Evaluation

- The biocompatibility evaluation for the body-contacting components of the Hair Removal 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, Document Issued on September 4, 2020", as recommended by FDA.

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, as per the following standards:

- 60601-1-2:2014+A1:2020: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility.
- IEC 60601-1:2005/AMD1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance .
- IEC 60601-1-11:2015/AMD1:2020 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 60601-2-83:2019/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 (first Eition) Photobiological safety of lamps and lamp systems.

4) Software Verification and Validation

Software documentation consistent with **Basic Documentation Level** 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.

5) Usability

The product usability has been evaluated and verified according to the following FDA guidance

- Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016.

IX. Conclusions

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