November 4, 2021

Shenzhen Century Dongyuan Technology Co Ltd.
℅ You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd.
Rm.1711, Building K, No.101 Science Ave
International Creative Valley
Guangzhou, Guangdong 510663
China

Re: K212897
Trade/Device Name: IPL Hair Removal Device, model: AI01
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: ONF
Dated: August 27, 2021
Received: September 10, 2021

Dear You Yijie:

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 (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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Purva Pandya
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212897

Device Name
IPL Hair Removal Device, model: AI01

Indications for Use *(Describe)*
The IPL Hair Removal Device (Model: AI01) is intended for the removal of unwanted body hair.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K212897

Section 5: 510(k) Summary

1. Submitter’s Information

Establishment Registration Information

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Date prepared: Oct. 20, 2021

2. Device Information

Trade Name:	IPL Hair Removal Device, model: AI01
Classification name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Common or Usual Name:	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Review panel:	General & Plastic Surgery
Product code:	ONF
Regulation Class:	II
Regulation Number:	878.4810

3. Predicate Device Information

510(k) submitter/holder:	Touchbeauty Beauty & Health (Shenzhen) Co., Ltd.
510(K) Number:	K183217
Trade Name:	IPL Hair Removal Device
Model:	TB-1755
Classification name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Review panel:	General & Plastic Surgery
Product code:	OHT, ONF
Regulation Class:	II
Regulation Number:	878.4810

4. Device description

IPL Hair Removal Device, model: AI01 is a 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 device is only powered by the external power adapter and its IPL emission activation is by finger switch. The device contains a Xenon Arc Flashlamp and a skin sensor to detect appropriate skin contact. If the device is not properly applied to the treatment area (in full contact with the skin), the device cannot emit the treatment light pulses. The device incorporates Intense Pulse Light (IPL) technology. The purpose of the light is to heat the root where the hair grows.

Device includes a main unit, an adaptor, and accessories, accessories include goggle.

Principle of operation:

The device works by use of thermal energy of Intense Pulse Light (IPL) to kill hair follicles for hair removal. The device generally targets skin (including dermis, epidermis), underlying soft tissue and hair follicles.

5. Indications for Use

The IPL Hair Removal Device (Model: AI01) is intended for the removal of unwanted body hair.

6. Summary of technological characteristics of device compared to the predicate devices (K183217)

SE Comparisons	**Subject device (IPL Hair Removal Device, model: AI01)**	**Predicate device (IPL Hair Removal Device, Model: TB-1755)**	**Discussion of difference**
510K Number	/	**K183217**	***/***
Classification	21CFR 878.4810	21CFR 878.4810	**Same**
Product Code	ONF	OHT, ONF	**Same**
FDA Class	II	II	**Same**
Indications for Use	The IPL Hair Removal Device (Model: AI01) is intended for the removal of unwanted body hair.	The IPL Hair Removal Device (Model: TB-1755) is an Over the Counter device intended for the removal of unwanted body hair.	**Same** (Discussion is indicated in D1)
Model	AI01	TB-1755	***/***
Environment of Use	Home use	Home use	**Same**
Design	Hand-hold	Hand-hold	**Same**
Patient Population	Adult	Adult	**Same**
Material of Patient contact components	PC	ABS	**Different** (Discussion is indicated in D2)
Biocompability testing	Meets ISO 10993- 5 ISO 10993-10	Meets ISO 10993- 5 ISO 10993-10	**Same**
Single Patient, multi-use	Yes	Yes	**Same**
Patient Interface	Buttons	Buttons	**Same**
Technology	Intense Pulse Light (IPL)	Intense Pulse Light (IPL)	**Same**
Dimensions	140*203*56	182*72.4*69.2mm	**Different** (Discussion is indicated in D3)
Power source	an external power supply	an external power supply	**Same**
Light source	Xenon Arc Flashlamp	Xenon Arc Flashlamp	**Same**
Wavelength	510nm~1100nm	510nm~1100nm	**Same**
Spot Size	3.1 cm^2	3.1 cm^2	**Same**
Max. Fluence (J/cm^2)	3.8-5.2 J/cm^2	3.8-5.2 J/cm^2	**Same**
Pulse duration	3 milliseconds	3 milliseconds	**Same**
Output energy	12-16 J	12-16 J	**Same**
Pulsing Control	Finger switch	Finger switch	**Same**
Output Channel	One channel	One channel	**Same**
Delivery	Direct Illumination to Tissue	Direct Illumination to Tissue	**Same**
Software	Yes	Yes	**Same**

Control			
Electrical safety, EMC, Biological Evaluation	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 60601-2-57 IEC 62471 ISO 10993-5 ISO 10993-10	**Same**

The discussion of differences exist between the subject and predicate devices is listed in following:

D1: The subject device has same indication with equivalent device regarding remove unwanted hair, the difference is that the equivalent device is for OTC use and the subject device is for Prescription Use, this difference does not raise new questions of safety.

D2: The subject device has been validated for cytotoxicity per ISO 10993- 5 and Irritation as well as Sensitization per ISO 10993-10 with positive results, therefore, the material difference of subject device with Predicate device TB-1755 (K183217) do not raise new questions of safety and effectiveness.

D3: The difference of dimensions will not affect the safety and effectiveness.

7. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1, IEC 60601-1-11 for safety, IEC 60601-1-2 for electromagnetic compatibility, IEC 60601-2-57:2011 for performance and IEC 62304 for software verification, and ISO 10993-5:2009 for Cytotoxicity endpoints, ISO 10993-10:2010 for Sensitization and Irritation endpoints are complied. See below table for details:

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2: 2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
IEC 60601-1-11: 2015	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral

	Standard: Electromagnetic Disturbances - Requirements And Tests
ISO 60601-2-57: 2011	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 62471: 2006	Photobiological safety of lamps and lamp systems
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
IEC 62304:2006+A1:2015	Medical device software - Software life cycle processes

Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

8. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

9. Conclusions

Based on performance testing, comparison and analysis, the subject device IPL Hair Removal Device, model AI01 is as safe, as effective, and performs as well as the legally marketed predicate device.