June 18, 2024

Shenzhen Beauty Every Moment intelligent electric Co., Ltd.
% Youshan Gong
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K240583
Trade/Device Name: IIPL Home Use Hair Removal Device (D-1199, D-T099, D-T018, D-T019, D-T003B, D-T003W, D-T018Y, D-T019Y, D-1196B, D-1196W, D-1196C, D-1196C1, D-T099K, D-T099KW, D-T012, D-T012W)
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: May 20, 2024
Received: May 20, 2024

Dear Youshan Gong:

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,

Tanisha L. Hithe -S
Digitally signed by Tanisha L. Hithe -S
Date: 2024.06.18 10:37:34 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240583

Device Name
IPL Home Use Hair Removal Device (D-1199, D-T099, D-T018, D-T019, D-T003B, D-T003W, D-T018Y, D-T019Y, D-1196B, D-1196W, D-1196C, D-1196C1, D-T099K, D-T099KW, D-T012, D-T012W)

Indications for Use *(Describe)*
IPL Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial 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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K240583 510(k) Summary

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

Date Prepared: 2024-6-14

I. Submitter

Shenzhen Beauty Every Moment intelligent electric Co., Ltd.
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II. Device

Name of Device: IPL Home Use Hair Removal Device
Model(s): D-1199, D-T099, D-T018, D-T019, D-T003B, D-T003W, D-T018Y, D-T019Y, D-1196B, D-1196W, D-1196C, D-1196C1, D-T099K, D-T099KW, D-T012, D-T012W
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

III. Predicate Device and Reference Device

➤ **Predicate Device**

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Beauty EveryMoment intelligent electric Co.,Ltd.	IPL Home Use Hair Removal Device, Model(s): D-1150, D-1171, D-1153, D-1155, D-1156, D-1126, D-1178, D-1187	K211185	December 20, 2021

➤ **Reference Device1**

Manufacturer	Reference Device	510(k) Number	Approval Date
Shenzhen IONKA Medical Technology Co., Ltd.	Hand-held IPL device (IPL Home Use Hair Removal Device), Model: FZ-608, FZ-608G, FZ-100, FZ-200	K230739	May 26, 2023

➤ **Reference Device2**

Manufacturer	Reference Device	510(k) Number	Approval Date
Foshan Jindi Electric Appliance Co.,Ltd	PL Home Use Hair Removal Device, Model(s): JD-TM002, JD-TM003, JDTM012, JD-TM016, JD-TM022	K231717	September 6, 2023

IV. Device Description

The IPL Home Use Hair Removal Device is the professional IPL in five levels or nine levels and offers a beauty experience in comfort of your own home as well as has been designed with unique features for simple, relaxed and effective hair removal.

IPL Home Use Hair Removal Device includes D-1199, D-T099, D-T018, D-T019, D-T003B, D-T003W, D-T018Y, D-T019Y, D-1196B, D-1196W, D-1196C, D-1196C1, D-T099K, D-T099KW, D-T012, D-T012W sixteen models. All have adopted basically identical structure design, consisting of IPL host and power adapter two parts, which the host is mainly composed of lamp cartridge, display screen, power and/or level button, indicator, skin sensor, fan, flash button and DC socket. D-T099K, D-T099KW, D-1196B, D-1196W do not contain the Ice-Cooling function. D-1199, D-T099, D-T018, D-T019, D-T003B, D-T003W, D-T018Y, D-T019Y, D-1196C, D-1196C1 have Ice-Cooling function and only perform the hair removal and cold compress function simultaneously. D-T012, D-T012W have Ice-Cooling function and it is able to perform the hair removal and cold compress function simultaneously or separately.

V. Indications for Use

IPL Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair.

VI. Materials

Model	Contacted Component Name	Materials
D-1199, D-T099, D-T018, D-T019, D-T003B, D-T003W, D-T018Y, D-T019Y, D-1196B, D-1196W, D-1196C, D-1196C1, D-T099K, D-T099KW, D-T012, D-T012W	Host of machine (including air outlet, treatment window, air inlet, buttons)	PC, ABS, PC+ABS Crystal, AL

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to Section "Biocompatibility Discussion"

VII. Comparison of Technological Characteristics With the Predicate Device

The IPL Home Use 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 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 Home Use Hair Removal Device may be found substantially equivalent to its predicate device.

IPL Home Use 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	Reference Device 1	Reference Device 2
Model	D-1199, D-T099, D-T018, D-T019, D-T003B, D-T003W, D-T018Y, D-T019Y, D-T099K, D-T099KW, D-1196C, D-1196C1, D-1196B, D-1196W, D-T012, D-T012W	D-1150, D-1171, D-1153, D-1155, D-1156, D-1126, D-1178, D-1187	FZ-608, FZ-608G,FZ-100,FZ-200	JD-TM002, JD-TM003, JD-TM012, JD-TM016, JD-TM022
510(k) Number	K240583	K211185	K230739	K231717
Trade name	IPL Home Use Hair Removal Device	IPL Home Use Hair Removal Device	Hand-held IPL device (IPL Home Use Hair Removal Device)	IPL Home Use Hair Removal Device

Comparison Elements	Subject device	Predicate Device	Reference Device 1	Reference Device 2
Manufacturer	Shenzhen Beauty Every Moment intelligent electric Co.,Ltd.	Shenzhen Beauty EveryMoment intelligent electric Co.,Ltd.	Shenzhen IONKA Medical Technology Co., Ltd.	Foshan Jindi Electric Appliance Co.,Ltd
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Product code	OHT	OHT	OHT	OHT
Device classification	Class II	Class II	Class II	Class II
Indication for use/ Intended use	IPL Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair.	IPL Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair.	IPL Home 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 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.

Comparison Elements	Subject device	Predicate Device	Reference Device 1	Reference Device 2
			the completion of a treatment regime.	
Prescription or OTC	OTC	OTC	OTC	OTC
Wavelength range	530-1100nm, 590-1100nm	Regular window: 530-1100nm, 590-1100nm Filter window: 600-1100nm	510nm~1200nm	JD-TM002,JD-TM003: 550-1100nm JD-TM012,JD-TM016: 600-1100nm JD-TM022: 640-1100nm
Energy density	2-6.18 J/cm2 (Error: +/-20%)	2.0~4.5 J/cm^2	FZ-608, FZ-608G: 3.33 J/cm2 FZ-100: 5.43 J/cm2 FZ-200: 4.5 J/cm2	JD-TM002,JDTM003,JD-TM012, JD-TM016: 2-5 J/cm^2 JD-TM022: 2-6 J/cm^2
Spot size	3.4 cm^2	Regular window: 3.8cm^2, 3.6cm^2, 3.0cm^2, 1.0cm^2, 2.0cm^2, 1.9cm^2, 1.8cm^2, Filter window: 3.0cm^2, 2.0cm^2	3.0cm^2	JD-TM002,JDTM003,JD-TM012: 3 cm^2 JD-TM016: 3.3 cm^2 JD-TM022: 4 cm^2
Pulse duration	0.725-1.283ms (+/-20%)	7.5~12ms	0.5~0.8 ms	8-12ms

VIII. 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 following 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 skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices –Part 23: Tests for skin irritation

2) Electrical Safety and EMC

Electrical safety and EMC 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 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Medical Electrical Equipment –Part 1: 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 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 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.

IX. Conclusions

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