January 14, 2022

Dongguan Define Beauty Electronic Technology Co. Ltd
℅ Helen Nan
General Manager
Cytech (Shenzhen) Enterprise Management Consulting Co.,Ltd.
Room B204, Building 12 Hourui 2nd Industrial Zone,
Bao'an District
Shezhen, Guangdong 518128
China

Re: K212318
Trade/Device Name: IPL Hair Removal SG-8025
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 7, 2021
Received: December 14, 2021

Dear Helen Nan:

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); 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)*
K212318

Device Name
IPL HAIR REMOVAL SG-8025

Indications for Use *(Describe)*
The IPL HAIR REMOVAL (Model: SG-8025) is an over the counter device intended for the removal of unwanted body and/or facial hair in adults. It is also intended for permanent reduction in unwanted hair.
Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6. 9. and 12 months after the completion of a treatment regimen.

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 K212318
(As required by 21 CFR 807.92(a))

1.0 Submitter Information

Company:	Dongguan Define Beauty Electronic Technology Co. Ltd.
Address	No.10 Xiangya Road, Jichiling Village, Dalingshan Town, Dongguan, Guangdong, 523812, CHINA
Phone:	0086-0769-89367468
Contact	Shaowu Wang
Title:	General Manager

· Date: January 13, 2022

2.0 Device Information

Trade/Device Name:	IPL HAIR REMOVAL SG-8025
Model:	SG-8025
Common Name:	IPL Hair Removal Device
Device:	Light Based Over-The-Counter Hair Removal
Definition:	Over-the-counter device uses thermal energy to kill hair follicles for hair removal.
Review Panel:	General & Plastic Surgery
Product Code:	OHT
Submission Type:	Traditional 510(k)
Regulation Number:	CFR 878.4810
Device Class:	Class II

3.0 Predicate Device Information

Trade/Device Name:	IPL Salon Hair Reduction System
510k Number:	K181568
Submitter:	Medical Device Branch of Zhangzhou Easepal Industrial Co.,Ltd.

4.0 Device Description

The IPL HAIR REMOVAL SG-8025 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 (IPL) technology. 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 it’s 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 applied to the treatment area (in full contact with the skin), the device cannot emit the treatment light pulses. The device is for single-person use only.

5.0 Indications for Use

The IPL HAIR REMOVAL (Model: SG-8025) is an over the counter device intended for the removal of unwanted body and/or facial hair in adults. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6. 9. and 12 months after the completion of a treatment regimen.

6.0 Comparison of Technological Characteristics with the Predicate Device Table

Table 1 - Device Comparison Table

Device Feature	Predicate Device	Subject Device
Trade Name	IPL Salon Hair Reduction System	IPL HAIR REMOVAL SG-8025
510k number	K181568	K212318
Classification Name	Light Based Over-The-Counter Hair Removal	
Regulation Number	CFR 878.4810	
Product code	OHT	
Use	OTC use	
Indication for use	The IPL Salon Hair Reduction System (Model: F60001) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6. 9. and 12 months after the completion of a treatment regimen.	The IPL Hair Removal (Model: SG-8025) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6. 9. and 12 months after the completion of a treatment regimen.
Device Type	Intense Pulsed Light	Intense Pulsed Light
Delivery device	Direct illumination to tissue	Direct illumination to tissue
Device Design		
Source Energy	Supplied by external adapter	Supplied by external adapter
Wavelength range	475-1200 nm	530 nm
Spot size	Regular window: 4.5cm² Facial adapter: 1.72cm²	3 cm²

Pulse duration	11-12 ms	1ms
Pulse control	Finger switch	Finger switch
Weight	650g	220g
Output Intensity Level	5 level	5 level
Max Energy density	Up to 5 J/cm²	2.5 J/cm²
Output energy with facial adapter	Level 1: 8.62J Level 2: 9.45J Level 3: 10.64J Level 4: 11.48J Level 5: 12.70J	Level 1: 7.5J Level 2: 8.5J Level 3: 9.5J Level 4: 11J Level 5: 12J
Dimensions	143*69.5*43mm(H*W*D)	205*76*56mm(H*W*D)
Software/Firmware/Microprocessor Control?	Yes	Yes
Standards		
60601 Compliance with Voluntary Standards	Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57	Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.
Electrical Safety	Comply with IEC60601-1 and IEC60601-2-57	Comply with IEC60601-1 and IEC60601-2-57

A brief summary of the similarities and differences between IPL Salon Hair Reduction System and IPL HAIR REMOVAL SG-8025 is included below:

Similarities:

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

Differences:

Basic Characteristics

"Weight", "Dimensions" is belong to basic characteristics. Although it is a little different from the predicate device, it will not affect the main function and the intended use of the device. They all also comply with IEC 60601-1 requirements. So the differences will not raise any safety or effectiveness issue.

Max Energy Density

Although the Max. Fluence of subject device is a little less than the the Predicate device, but they all comply with IEC 60601-1, IEC 60601-2-57 requirement. So the differences of function specification will not raise any safety or effectiveness issue.

Pulse Duration

Although the Pulse Duration of subject device is less than the predicate device, the subject device comply with all electrical safety eye safety and EMC Standard, So the differences of pulse duration time will not raise any safety or effectiveness issue.

Wavelength

Although the wavelength of subject device is a little different from the predicate devices, but they all comply with IEC 60601-1, IEC 60601-2-57 requirement. And the wavelength of subject device is in the range of the one of predicted device. So the differences of function specification will not raise any safety or effectiveness issue.

Spot Size

There is minor difference in Spot size between the subject device and the predicate devices. And they all comply with IEC 60601-1, IEC60601-2-57 requirement. So the differences of Spot size will not raise any safety or effectiveness issue.

7.0 Non- Clinical Performance Data

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

7.1 Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the IPL Home Use Hair Remover 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 June 16, 2016", as recognized by FDA. The battery of testing was performed to, and passed, including:

- ISO 10993-5:2009/(R)2014, Biological Evaluation of Medical Devices –Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010/(R)2014, Biological Evaluation of Medical Devices –Part 10: Tests for Irritation and Skin Sensitization

7.2 Electrical Safety

- Electrical safety and Eye safety testing was performed to, and passed, the following standards:

- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- 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 60601-2-57 Medical electrical equipment –Part 2-57: Particular requirements for the basic safety and essential performance of non-laser source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

7.3 Eye Safety

- IEC 62471 Photobiological safety of lamps and lamp systems
- ISO 14971 Medical Devices – Applications of Risk Management to Medical Devices

7.4 Software Verification and Validation

- Software documentation consistent with **moderate level** of concern 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.

Based on the above performance as documented in this application, IPL HAIR REMOVAL SG-8025 was found to have a safety and effectiveness profile that is similar to the predicate devices.

8.0 Clinical Performance Data

No clinical tests was performed on the subject device.

9.0 Conclusion:

IPL HAIR REMOVAL SG-8025 was found to be substantially equivalent to the predicate devices and shares the same or similar indications for use, design, operational and functional features as the predicate devices. Any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness.