April 6, 2023

Shenzhen BSX Technology Electronics Co., Ltd.
℅ Riley Chen
Registration engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K230097
Trade/Device Name: IPL Hair Removal Device, Model(s): BSXT101, BSXT102, BSXT103, BSXT105, BSXT106, BSXT108
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 28, 2022
Received: January 13, 2023

Dear Riley Chen:

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,

Colin K. Chen -S

for

Jianting Wang
Acting 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)*
/

Device Name
IPL Hair Removal Device
Model(s): BSXT101, BSXT102, BSXT103, BSXT105, BSXT106, BSXT108

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

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

I. Submitter

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II. Device

Name of Device: IPL Hair Removal Device
Model(s): BSXT101, BSXT102, BSXT103, BSXT105, BSXT106, BSXT108
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

Primary predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Medical Device Branch of Zhangzhou Easepal Industrial Co.,Ltd.	IPL Salon Hair Reduction System (Model: F60001)	K181568	Sep. 11, 2018

Reference devices:

Manufacturer	Reference Device	510(k) Number	Approval Date
Shenzhen Junbobeauty Technology Co., Ltd.	IPL HAIR REMOVAL HANDSET, Model: IPL-666	K220669	May 16, 2022
Shenzhen Leaflife Technology Co., Ltd	Leaf Smooth	K212697	Nov. 19, 2021

IV. Device Description

IPL Hair Removal Device (Model: BSXT101, BSXT102, BSXT103, BSXT105, BSXT106, BSXT108), is an over-the-counter, home-use and personal device for hair reduction by using

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 (a.c.100~240V 50/60Hz) and its IPL emission activation is by finger switch. It contains a skin sensor to detect appropriate skin contact, if the Light Outlet of the device is not in full contact with the skin, the device cannot trigger a light pulse. The device have six models and these models share the same performance, structure and operation, the only difference is their enclosure color.

V. Indications for Use

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

VI. Materials

Component name	Material of Component	Body Contact Category	Contact Duration
IPL Hair Removal Device	ABS	Surface-contacting device: Intact skin	Less than 24 hours

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to Section 16 "Biocompatibility Discussion".

VII. Comparison of Technological Characteristics With the Predicate Device

The IPL Hair Removal Device has the same intended use as the predicate and reference devices. The technological characteristics such as wavelength, energy density, spot size and pulse duration, are similar to the predicate device and reference devices. Any minor differences between the subject device and the listed predicate device and reference 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 and reference devices for its intended use. Therefore, the IPL Hair Removal Device may be found substantially equivalent to its predicate device and reference devices.

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Remark**
510(k) Number	Pending	K181568	K220669	K212697	/
Trade name	IPL Hair Removal Device	IPL Salon Hair Reduction System, Model: F60001	IPL HAIR REMOVAL HANDSET Model: IPL-666	Leaf Smooth	/
Manufacturer	Shenzhen BSX Technology Electronics Co., Ltd.	Medical Device Branch of Zhangzhou Easepal Industrial Co.,Ltd.	Shenzhen Junbobeauty Technology Co., Ltd.	Shenzhen Leaflife Technology Co., Ltd	/
Regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Remark**
number					
Product code	OHT	OHT	OHT	OHT	Same
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	The IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/ or facial hair.	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.	IPL HAIR REMOVAL HANDSET is an over-the-counter device intended for removal of unwanted body and/or facial hair.	The Leaf Smooth is an over-the-counter device intended for removal of unwanted body and/or facial hair.	Same
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick Skin Types I-V	/	Fitzpatrick Skin Types I-V	/	Same
Device design					
Source energy	Supplied by external adapter	Supplied by external adapter	Powered by external power adapter	Supplied by external adapter	Same
Power supply	100-240V, 50/60Hz	100-240V AC; 50/60 Hz	100~240V AC Input 12V3A DC Output	/	Same
Dimension	190 x 70 x 45 mm	143*69.5*43mm (H*W*D)	124*83*48.5mm	/	Different
Weight	Approx. 225 g	650g	186g	/	Different
Sterilization	Not required	Not required	Not required	Not required	Same
Output specification					
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp	Xenon Arc Flashlamp	Xenon Quartz Tube	Xenon Arc Flashlamp	Same
Wavelength range	470nm-1200nm	475nm~1200nm	470nm ~1100nm	475-1100nm	Similar

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Remark**
Energy density	Max 5.0 J/cm²	Max 5.0 [J/cm²]	1.3~2.49J/cm²	4-6J/cm²	Similar
Spot size	3.0cm² ± 0.5cm²	1.72 cm² or 3.02 cm²	3cm²	3.8cm²	Same
Pulse duration	4-10ms	11-12 ms	11.5-15ms	2-10ms	Similar
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Output intensity level	5 Levels	5 Levels	5 Levels	6 Levels	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Same
Additional features					
Electrical safety	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	Same
Eye safety	IEC 62471	/	IEC 62471	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO10993-5 ISO10993-10	ISO10993-5 ISO10993-10	ISO 10993-5 ISO 10993-10	Same

VIII. Non-clinical studies and performance data

Non-clinical tests were conducted to verify that the IPL Hair Removal Device meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device and reference devices. The test results demonstrated that the subject device complies with the following standards:

1) Biocompatibility Testing

The device has been tested for biocompatibility, it complies with the following standards:

- ISO 10993-5:2009, Biological Evaluation of Medical Devices –Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices –Par t 10: Tests for Irritation and Skin Sensitization

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, as per 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
- ANSI AAMI ES60601-1 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 60601-2-83 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 verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"

5) Usability

The product usability has been evaluated and verified according to the 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 IPL Hair Removal Device is as safe, as effective, and performs as well as the legally marketed predicate device and reference devices.