June 15, 2025

Bestway Plastic And Metal Products Ltd.
% Candice Qiu
Registration Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K243036
Trade/Device Name: IPL Hair Removal Device (BHRL-01, BHRL-02, BHRL-03, BHRL-04, BHRL-05, BHRL-06, BHRL-06B, BHRL-07, BHRL-08, BHRL-09, BHRL-10, BHRL-11, BHRL-12, BHRL-13, BHRL-14, BHRL-15, BHRL-16, BHRL-17, BHRL-18, BHRL-19, BHRL-20, BHRL-21, BHRL-22.
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 23, 2025
Received: May 23, 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 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.

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: 2025.06.15 19:58:49 -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243036

Device Name

IPL Hair Removal Device (BHRL-01, BHRL-02, BHRL-03, BHRL-04, BHRL-05, BHRL-06, BHRL-06B, BHRL-07, BHRL-08, BHRL-09, BHRL-10, BHRL-11, BHRL-12, BHRL-13, BHRL-14, BHRL-15, BHRL-16, BHRL-17, BHRL-18, BHRL-19, BHRL-20, BHRL-21, BHRL-22)

Indications for Use *(Describe)*

IPL 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

K243036

"510(k) Summary" as required by 21 CFR Part 807.92.
June 6, 2025

I. Submitter

Bestway Plastic And Metal Products Ltd.
Room 701, Building 2, No.1 Chuangye San Road, Mapu Ao, Fenggang Town, Dongguan City, Guangdong Province, China
Jonah Ci
General Manager
Tel: +86 13412459592
Email: Jonah@pm-bestways.com

II. Device

Name of Device: IPL Hair Removal Device
Model(s): BHRL-01, BHRL-02, BHRL-03, BHRL-04, BHRL-05, BHRL-06, BHRL-06B, BHRL-07, BHRL-08, BHRL-09, BHRL-10, BHRL-11, BHRL-12, BHRL-13, BHRL-14, BHRL-15, BHRL-16, BHRL-17, BHRL-18, BHRL-19, BHRL-20, BHRL-21, BHRL-22.
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 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 device:

Manufacturer	Reference Device	510(k) Number	Approval Date
Shenzhen BSX Technology Electronics Co., Ltd.	IPL Hair Removal Device Model(s): BSXT101, BSXT102, BSXT103,	K230097	April 6, 2023

Manufacturer	Reference Device	510(k) Number	Approval Date
	BSXT105, BSXT106, BSXT108		

IV. Device Description

IPL 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 twenty-three models with the same IPL technology for hair removal, which is model BHRL-01, BHRL-02, BHRL-03, BHRL-04, BHRL-05, BHRL-06, BHRL-06B, BHRL-07, BHRL-08, BHRL-09, BHRL-10, BHRL-11, BHRL-12, BHRL-13, BHRL-14, BHRL-15, BHRL-16, BHRL-17, BHRL-18, BHRL-19, BHRL-20, BHRL-21, BHRL-22. 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 IPL Hair Removal Device has an irreplaceable light exit and it can cover an area of 3.6±0.25cm^2 (Model BHRL-01, BHRL-02, BHRL-03, BHRL-04, BHRL-07, BHRL-08, BHRL-09, BHRL-10) and 2.7±0.25cm^2 (Model BHRL-05, BHRL-11, BHRL-12, BHRL-13, BHRL-14, BHRL-15, BHRL-16, BHRL-17, BHRL-06, BHRL-06B, BHRL-18, BHRL-19, BHRL-20, BHRL-21, BHRL-22) that is suitable for multiple hair removal areas, such as large areas (e.g. face, arms, legs) and small areas (e.g. armpits, bikini line).

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 IPL Hair Removal Device has the cooling function (except model: BHRL-06B), which can 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

IPL 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

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

VII.Comparison of Technological Characteristics With the Predicate Device

The IPL 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 not 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 IPL Hair Removal Device may be found substantially equivalent to its predicate device and reference device.

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

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Remark**
510(k) Number	Pending	K230739	K230097	/
Trade name	IPL Hair Removal Device Model: BHRL-01, BHRL-02, BHRL-03, BHRL-04, BHRL-05, BHRL-06, BHRL-06B,BHRL-07, BHRL-08, BHRL-09, BHRL-10, BHRL-11, BHRL-12, BHRL-13, BHRL-14, BHRL-15, BHRL-16, BHRL-17, BHRL-18, BHRL-19, BHRL-20, BHRL-21, BHRL-22	Hand-held IPL device (IPL Home Use Hair Removal Device) Model: FZ-608, FZ-608G, FZ-100, FZ-200	IPL Hair Removal Device Model(s): BSXT101, BSXT102, BSXT103, BSXT105, BSXT106, BSXT108	/
Manufacturer	Bestway Plastic And Metal Products Ltd.	Shenzhen IONKA Medical Technology Co., Ltd.	Shenzhen BSX Technology Electronics 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	IPL Hair Removal Device is indicated for the removal of unwanted hair. The device is also indicated for the permanent	IPL Home Use Hair Removal Device is indicated for the removal of unwanted hair. The device is also indicated for the	The IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/ or facial	Same

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Remark**
	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.	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.	hair.	
Prescription or OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick skin types I-V	Unknown	Fitzpatrick Skin Types I-V	Same
Dimension	BHRL-01, BHRL-02, BHRL-03, BHRL-04, BHRL-07, BHRL-08, BHRL-09, BHRL-10: 80*180*170mm BHRL-05, BHRL-11, BHRL-12, BHRL-13, BHRL-14, BHRL-15, BHRL-16, BHRL-17: 70*170*40mm BHRL-06, BHRL-06B, BHRL-18, BHRL-19, BHRL-20, BHRL-21, BHRL-22: 60*180*30mm	FZ-608, FZ-608G: 98*147*60(mm) FZ-100: 198*71*44(mm) FZ-200: 216*68*52(mm)	190x70x45mm	Difference
Power supply	100-240V, 50/60Hz, 0.8AMax	Unknown	100-240V, 50/60Hz	Same
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 lamp	Same
Wavelength range	510-1200±15nm	550-1200mm	470nm-1200nm	Similar
Energy density	1.2-4.1 J/cm^2	FZ-608, FZ-608G: 3.33 J/cm^2 FZ-100: 5.43 J/cm^2 FZ-200: 4.5 J/cm^2	Max 5.0 J/cm^2	Similar

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Remark**
Output energy	4.5 ~ 10J (±20%)	FZ-608, FZ-608G: Level 1: 4.16J Level 2: 4.36J Level 3: 5.1J Level 4: 6.1J Level 5: 6.96J Level 6: 7.96J Level 7: 8.63J Level 8: 9.13J Level 9: 10.0J	Pure mode: 5~10J (±20%) Armpit mode: 6~10J (±20%) Body mode: 6.5~11J (±20%) Bikini mode: 8~12.5J (±20%)	Similar
Spot size	(1) Model BHRL-01, BHRL-02, BHRL-03, BHRL-04, BHRL-07, BHRL-08, BHRL-09, BHRL-10: 3.6±0.25cm^2 (2) Model BHRL-05, BHRL-11, BHRL-12, BHRL-13, BHRL-14, BHRL-15, BHRL-16, BHRL-17, BHRL-06, BHRL-06B, BHRL-18, BHRL-19, BHRL-20, BHRL-21, BHRL-22: 2.7±0.25cm^2	3cm^2	3.0cm^2± 0.5cm^2	Similar
Pulse duration	6.4±2.0ms	0.5-0.8ms	4-10ms	Similar
Pulsing control	Finger switch	Finger switch	Finger switch	Same
Output intensity level	5 Levels		5 Levels	Different
Software/ Firmware/ Microprocessor Control?	Yes	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 60601-2-83	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	Same
Eye safety	IEC 62471	IEC 62471	IEC 62471	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 IPL 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 recognized by FDA.

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.
- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance .
- IEC 60601-1-11 Medical electrical equipment - Part 1-11: 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 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*** 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.

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 IPL Hair Removal Device is as safe, as effective, and performs as well as the legally marketed predicate device and reference device.