September 23, 2024

Shenzhen Yang Wo Electronic 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: K241834
Trade/Device Name: IPL Hair Removal Device (BE932C, BE932D, BE932E)
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: June 24, 2024
Received: June 25, 2024

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 (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: 2024.09.23 22:25:54 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
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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)*

K241834

Device Name

IPL Hair Removal Device (BE932C, BE932D, BE932E)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Prepared on: 2024-09-23

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact	Ms. Riley Chen
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	IPL Hair Removal Device (BE932C, BE932D, BE932E)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Light Based Over-The-Counter Hair Removal
Regulation Number	878.4810
Product Code(s)	OHT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220645	Hand-held IPL device (JOVS Hair Removal Device)	OHT
K230122	IPL Hair Removal Device	OHT
K192432	IPL Home Use Hair Removal Device	OHT

Device Description Summary

21 CFR 807.92(a)(4)

IPL Hair Removal Device is an over-the-counter, light based device for unwanted hair reduction by using Intense Pulsed Light (IPL) technology. The device works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain.

The device includes three models with the only difference in enclosure color. It is only powered by the external power adapter and its IPL emission activation is by a switch or auto light emission, and it contains a skin sensor to detect appropriate skin contact, if the flash window is not in full contact with the skin, the device cannot emit the treatment light pulses. The device has a cooling function for a better hair remove experience.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device and the primary predicate device have the same indications for use, they are both over-the-counter devices intended for removal of unwanted body and/ or facial hair.

Technological Comparison 21 CFR 807.92(a)(6)

The technological characteristics of the subject device and predicate devices (K220645 and K230122) and reference device (K192432) are substantially equivalent in the following aspects:
1. Design: hand-held
2. Energy source: power by external power adapter, input 100-240V, 50/60Hz
3. Energy medium: Xenon Arc Flashlamp
4. Light source: Intense Pulsed Light (IPL)
5. The following main output parameters are similar with the predicates and the reference device:
   a) the wavelength (600~1200nm) of the subject device is within the range of the primary predicate device, K220645 (590~1200nm);
   b) the output energy is within the range of the primary predicate device (K220645) and the energy density is in the range of the secondary predicate device (K230122);
   c) the pulse duration is within the range of the reference device (K192432)

The main difference between the subject device and the predicates and reference devices is product dimensions, but this difference is insignificant and do not raise any safety or effectiveness problems.

Thus, the subject device is determined to be substantially equivalent to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testings have been 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 devices. The testing results demonstrate that the subject device complies with the following standards:
- IEC 60601-1: 2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2020, 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: 2020, 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: 2022, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62471: 2006, Photobiological safety of lamps and lamp systems

The device has been tested for biocompatibility, it complies with the following standards.
- ISO 10993-5: 2009, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro 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 irritation

We have also conducted:
- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"

The product usability has been evaluated according to "Applying Human Factors and Usability Engineering to Medical Devices"

The clinical test is not applicable, there is no clinical data.

The subject device is as safe, as effective, and performs as well as the predicate devices.