October 21, 2021

Zhongshan Bisen Plastic Electronic Products Co., Ltd.
℅ Mark Leung
Consultant
Shenzhen Joyantech Consulting Co.,Ltd.
1713A, Block A, Zhongguan Times Square
Liuxian Avenue, Xili Town
Shenzhen, Guangdong 518000
China

Re: K212314
Trade/Device Name: IPL Hair Removal Device
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: July 16, 2021
Received: July 23, 2021

Dear Mark Leung:

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 and Part 809; 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)*
K212314

Device Name
IPL Hair Removal Device

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

## 1. Administrative Information

| | |
|---|---|
| **Submission Date** | July 16, 2021 |
| **Manufacturer information** | Zhongshan Bisen Plastic Electronic Products Co., Ltd.<br>Address:<br>Second Floor, A Building, No.32 JianYe Road, Torch Development Zone<br>Zhongshan City Guangdong, CN 528437.<br><br>Contact person: Rao Guanhua<br>TEL: +86(760)88297142<br>E-Mail: 376299441@qq.com |
| **Submission Correspondent** | Shenzhen Joyantech Consulting Co., Ltd.<br>1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China.<br>Contact person: Mr. Mark Leung; Mr. Field Fu<br>E-Mail: mark_leung@cefda.com; field@cefda.com |
| **Establishment registration number** | 3010564031 |

## 2. Device Information

| | |
|---|---|
| **Type of 510(k) Submission:** | Traditional |
| **Device Name:** | IPL Hair Removal Device |
| **Model:** | BZ-0721 |
| **Classification Name:** | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| **Review Panel:** | General & Plastic Surgery |
| **Device Class:** | 2 |
| **Regulation Number:** | 878.4810 |
| **Product Code:** | OHT |

## 3. Predicate Device

| | |
|---|---|
| **Manufacturer:** | Shenzhen Bosidin Technology Co.,Ltd. |
| **Device Name:** | IPL Home Use Hair Removal Device |
| **Model:** | D-1128 |
| **510(K) Number:** | K192432 |
| **Product Code:** | OHT |

## 4. Device Description

The IPL Hair Removal Device is a light-based device and an over-the-counter device which is expected to be sold directly to end users. The device provides hair reduction using Intense Pulsed Light (IPL) technology. The purpose of the light is to heat the root where the hair grows. 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 its IPL emission activation is by finger switch. The device has two working modes, an automatic mode and a manual mode. Each mode has 5 levels of output energy. The device contains a Xenon lamp that emits pulses of light (a total of 350000 pulses over the device’s lifetime) 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), it will cannot emit the treatment light pulses.

## 5. Intended Use/Indications for Use

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

## 6. Comparison with predicate device

| ID | Comparison Items | Subject Device | Predicate Device (K192432) | Comparison |
|---|---|---|---|---|
| 1 | **Device name** | IPL Hair Removal Device | IPL Home Use Hair Removal Device | / |
| 2 | **Model** | BZ-0721 | D-1128 | / |
| 3 | **Classification Name** | Laser surgical instrument for use in general and plastic surgery and dermatology | Laser surgical instrument for use in general and plastic surgery and dermatology | Same |
| 4 | **Product Code** | OHT | OHT | Same |
| 5 | **Regulation Number** | 878.4810 | 878.4810 | Same |
| 6 | **Class** | II | II | Same |
| 7 | **Prescription or OTC** | OTC | OTC | Same |
| 8 | **Indications for Use** | The IPL 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. | Same |
| 9 | **Source Energy** | Supplied by external adapter | Supplied by external adapter | Same |
| 10 | **Technology** | Intense Pulsed Light (IPL) | Intense Pulsed Light (IPL) | Same |
| 11 | **Energy medium** | Xenon lamp | Xenon lamp | Same |
| 12 | **Pulsing Control** | Finger switch | Finger switch | Same |
| 13 | **Delivery device** | Direct illumination to tissue | Direct illumination to tissue | Same |

| ID | Comparison Items | Subject Device | Predicate Device (K192432) | Comparison |
|---|---|---|---|---|
| 14 | **Wavelength** | 510nm~1100nm | Regular window: 510-1100nm<br>Filter window: 600-1100nm | Comparable<br>(1) See below |
| 15 | **Energy density** | 1.5-3.0 J/cm² | 2.0~4.0J/cm² | Comparable<br>(2) See below |
| 16 | **Spot Size** | 4cm² | Regular window: 4.5cm², 2.0cm², 3.0cm²<br>Filter window:2.5cm² | Comparable<br>(3) See below |
| 17 | **Output energy** | 6.0J ~ 11.8J | 4.0J ~ 18.0J | Comparable<br>(4) See below |
| 18 | **Pulse duration** | 10.4ms | 7.5~14ms | Comparable<br>(5) See below |
| 19 | **Weight** | 333g | Unknown | Comparable<br>(6) See below |
| 20 | **Dimension** | 169.0x81.0x197.0mm (H x W x D) | Unknown | Comparable<br>(6) See below |
| 21 | **Applicable standards** | ANSI AAMI 60601-1<br>IEC 60601-1-11<br>IEC 60601-1-2<br>IEC 60601-2-57<br>ISO 10993-5<br>ISO 10993-10 | IEC 60601-1<br>IEC 60601-1-11<br>IEC 60601-1-2<br>IEC 60601-2-57<br>ISO 10993-5<br>ISO 10993-10 | Same |

| ID | Comparison Items | Subject Device | Predicate Device (K192432) | Comparison |
|---|---|---|---|---|
| | | IEC 62471 | IEC 62471 | |

**Note:**

**(1) Wavelength:**

The wavelength range differences between the subject and predicate device do not raise new concerns of safety and effectiveness for the power output levels.

**(2) Energy density:**

The energy density range differences between the subject and predicate device do not raise new concerns of safety and effectiveness. The energy density is the amount of light energy delivered per unit area. The energy density range is calculated according to the following formula:

$$\textbf{Energy density}(\textbf{J/cm2}) = \frac{\textbf{Output energy (J)}}{\textbf{Spot Size (cm2)}}$$ ----------***Formula 1***

**(3) Spot Size:**

For the output spot size, there is a minor difference between the subject device and the predicate device. The spot size differences between the subject and predicate devices do not raise new concerns of safety and effectiveness.

**(4) Output energy:**

The energy density is the amount of light energy delivered per unit area. According to the following formula, the output energy can be calculated.

$$\text{Output energy (J)} = \text{Energy density(J/cm2)} \times \text{Spot Size (cm2)} \quad \textbf{----------}\textit{Formula 2}$$

The output energy range of predicate device is 4.0J~18.0J. The output energy of subject device is within the range of predicate device. The output energy differences between the subject and predicate devices do not raise new concerns of safety and effectiveness.

**(5) Pulse duration:**

The pulse duration range of subject device is within the range of predicate device. The pulse differences between the subject and predicate devices do not raise new concerns of safety and effectiveness.

**(6) Weight and Dimension:**

The weight and dimension differences between subject and predicate devices do not raise new concerns of safety and effectiveness.

# 7. Non-Clinical Test Summary

## 7.1. Electromagnetic Compatibility and Electrical Safety Test

The subject device has passed safety and performance testing in according to following standards.

1) ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2) IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3) IEC 60601-1-11:2015 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
4) IEC 60601-2-57:2011 Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
5) IEC 62471:2006 Photobiological safety of lamps and lamp systems

## 7.2. Biocompatibility Test

The subject device has passed biocompatibility tests in according to following standards.

1) ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2) ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

## 7.3. 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.

# 8. Clinical Study

No new clinical performance data is reported in this submission.

# 9. Conclusion

The technological characteristics and indications for use for the subject device (IPL Hair Removal Device [Model: BZ-0721]) do not raise new types of questions regarding safety and effectiveness when compared to the predicate device (K192432). Based on its

technical characteristics, design, functional features, performance test data, and its indications for use as listed above, the subject device is considered to be substantially equivalent to the predicate device.