February 26, 2021

Shenzhen Weikai Technology CO.,LTD
% Rain Yip
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm2401, ZhenYe International Center,
No.3101-90 Qianhai Road, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K203510
Trade/Device Name: IPL Hair removal
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: November 11, 2020
Received: November 30, 2020

Dear Rain Yip:

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 U. Pandya -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203510

Device Name
IPL Hair removal
V501, V201, V301-s, V401

Indications for Use *(Describe)*
IPL Hair removal is an over-the-counter device intended for removal of unwanted body hair 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

K203510

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

Date: 2020-11-11

I. Submitter

Shenzhen Weikai Technology CO.,LTD
Rm.101&201, Bldg.4, Haoer Jiashitai Technology Park, Fengtang Avenue No.164, Heping Community, Fuhai Street, Bao'an District, Shenzhen, Guangdong, China
Post code: 518118
Tel.: +86 0755 8337 4619

LI JING
General Manager
Tel: +86 180 1876 9288
Email: 50917560@qq.com

II. Device

Name of Device: IPL Hair removal
Model(s): V501, V201, V301-s, V401
Common or Usual Name: Light Based Over-The-Counter Hair Removal
Classification 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

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Bosidin Technology Co.,Ltd.	IPL Home Use Hair Removal Device/D-1128	K192432	Nov.8, 2019
Shen Zhen CosBeauty Co., Ltd	PerfectSmooth/CB-014	K161428	Mar. 23, 2017
CyDen Limited.	iPulse SmoothSkin Gold Hair Removal System	K160968	Apr.14, 2016

IV. Device Description

The IPL Hair removal 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. The device consists of IPL main body and power adapter two parts, and

treatment window located in the main body which is the source of optical radiation, namely a Xenon Arc flashlamp; and the device is power from power adapter via an external power.

The IPL Hair removal includes V501, V201, V301-s, and V401 four models. Their intended use, performance, circuit principle, structure design and operation are basically identical, with the differences contains the appearance of the product , the size of PCB board and LCD display contents; and these differences do not affect or change the intended use of the device.

V. Indications for Use

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

VI. Comparison of Technological Characteristics With the Predicate Device

The IPL Hair removal 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.
IPL Hair removal is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance:
1) K192432, "IPL Home Use Hair Removal Device/D-1128", manufactured by "Shenzhen Bosidin Technology Co.,Ltd. " in Guangdong, China
2) K161428, "PerfectSmooth", manufactured by "Shen Zhen CosBeauty Co., Ltd" in Guangdong, China
3) K160968, "iPulse SmoothSkin Gold Hair Removal System", manufactured by "CyDen Limited" in Wales, UK

Comparison Elements	**Subject Device**	**Predicate Device**		
		K192432 (Primary)	**K161428**	**K160968**
K Number	Pending	K192432	K161428	K160968
Trade name	IPL Hair removal	IPL Home Use Hair Removal Device	PerfectSmooth	iPulse SmoothSkin Gold Hair Removal System
Wavelength range	530-1200nm	Regular window: 510-1100nm Filter window: 600-1100nm	≥510nm	510-1100nm
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Energy density	3.0~4.0J/cm ²	2.0~4.0J/cm ²	4.7 J/cm ²Max.	3~6 J/cm ²
Spot size	3.7cm ²	Regular window:	4.5 cm ²	3 (3cm by 1cm)

Comparison Elements	**Subject Device**	**Predicate Device**		
		K192432 (Primary)	**K161428**	**K160968**
		4.5cm ², 2.0cm ² Filter window: 2.5cm ²		
Pulse duration	4~13ms	7.5~14ms	11-13ms	2-10ms
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch
Delivery device	Direct illumination to tissue	Direct illumination tissue	Direct illumination to tissue	Direct illumination tissue
Indication for use/Intended use	IPL Hair removal is an over-the-counter device intended for removal of unwanted body hair 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.	The PerfectSmooth is an over-the-counter device intended for removal of unwanted hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs.	The iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse Smoothskin Gold 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.
Location for use	OTC	OTC	OTC	OTC

VII.Performance Data

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

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the IPL Hair removal 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 –Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010/(R)2014, Biological Evaluation of Medical Devices –Par t 10: Tests for Irritation and Skin Sensitization

2) Electrical Safety and Eye 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

3) Eye Safety

- IEC 62471 Photobiological safety of lamps and lamp systems

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.

Summary

Based on the above performance as documented in this application, IPL Hair removal was found to have a safety and effectiveness profile that is similar to the predicate devices.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the IPL Hair removal is to be concluded substantial equivalent to its predicate devices.