December 7, 2023

Shenzhen MEIK Beauty Industry Co., Ltd
% Rain Yip
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 ZhenYe International Center, No. 3101-90
Qianhai Road, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K232846
Trade/Device Name: Light Based 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: September 14, 2023
Received: September 14, 2023

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 (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.

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
2023.12.07 21:33:24 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Light Based Hair Removal Device, Model(s): A113, A112, AM001

Indications for Use *(Describe)*
Light Based Hair Removal Device is an over-the-counter device intended for removal of unwanted body 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

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

Date: 2023-12-01

I. Submitter

Shenzhen MEIK Beauty Industry Co., Ltd
Building 202, Building A, Hejing Industrial Zone, High tech Park, Zhancheng Community, Fuhai Street, Bao'an District, Shenzhen, Guangdong, China
Post code: 518100
Tel.: +86 755 3287 8811

Xuegang Zhang
General Manager
Tel.: + 86 134 3076 0688
Email: MEIKBeauty@outlook.com

II. Device

Name of Device: Light Based Hair Removal Device
Model(s): A113, A112, AM001
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

Predicate device:
510(k) number: K230097
Manufacturer: Shenzhen BSX Technology Electronics Co., Ltd.
Trade name: IPL Hair Removal Device, BSXT101
Product code: OHT
Approval date: April 6, 2023

Reference device 1:
510(k) number: K212697
Manufacturer: Shenzhen Leaflife Technology Co., Ltd
Trade name: Leaf Smooth (LH-LIPLB)
Product code: OHT
Approval date: November 19, 2021

Reference device 2:

510(k) number: K161565
Manufacturer: STETIC MEDICAL AESTHETICS DEVELOPMENT (SHENZHEN) CO., LTD
Trade name: DUO, Model: IPL-HH380-IT
Product code: ONF
Approval date: September 1, 2016

IV. Device Description

The Light Based Hair Removal Device 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, and it works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain.

The Light Based Hair Removal Device is only powered by the external power adapter and its IPL emission activation is by finger switch. The device contains a Xenon lamp and its built-in skin sensor to detect appropriate skin contact. If the device is not properly and fully applied to the treated skin, the device will not emit the light pulse.

There are A113, A112, and AM001 three models in this application. Their work principle, function, intended use, structure, and composition are the same, with differences being product appearance, size, and energy output density are slight differences, but these parameters are within the predicate device and do not affect or change the intended use of the device.

V. Indications for Use

Light Based Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair.

VI. Comparison of Technological Characteristics With the Predicate Device

The subject device Light Based 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 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 subject device may be found substantially equivalent to its predicate device.
The subject device is compared with the following Predicate Device in terms of intended use, design, specifications, and performance:

Comparison Elements	**Subject Device**	**Predicate device K230097**	Reference device 1 K212697	Reference device 2 K161565
K Number	Pending	K230097	K212697	K161565
Trade name	Light Based Hair Removal Device/model: A113, A112, and	IPL Hair Removal Device, BSXT101	Leaf Smooth (LH-LIPLB)	DUO, Model: IPL-HH380-IT

Comparison Elements	**Subject Device**	**Predicate device K230097**	Reference device 1 K212697	Reference device 2 K161565
	AM001			
Wavelength range	470~1100nm	470~1200nm	475~1100nm	480~1200nm
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Energy density	Range in 2.0~4.6J/cm² and its error is ±10%, each model in this application corresponds to the following: A113: 2.0~3.9J/cm² AM001, A112: 2.1~4.6J/cm²	Max. 5.0J/cm²	4~6J/cm^2	5 J/cm^2
Spot size	A113: 4cm² AM001, A112: 3cm²	(3.0+/-0.5)cm²	3.8cm^2	3 cm^2
Pulse duration	3~12ms	4~10ms	2-10ms	＜20ms
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination tissue	Direct illumination tissue
Indication for use/Intended use	Light Based Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair.	The IPL Hair Removal Device 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	The DUO (Model: IPL-HH380-IT) is and over the Counter device intended for the removal of unwanted body and/or facial hair in adults. The DUO 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 regrowing when measured at 6.9. and 12 months after the completion of a treatment regimen.
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 Safety

The materials of the patient-directly contacting components of the subject device was performed the biocompatibility evaluation 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 Sep. 4, 2020", as recognized by FDA. The battery of testing was performed to, and passed, including:

- ISO 10993-5 Biological Evaluation of Medical Devices –Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices –Part 10: Tests for Skin Sensitization
- ISO 10993-23 Biological Evaluation of Medical Devices –Part 23: Tests for Irritation

2) Electrical Safety and EMC

Electrical safety and EMC 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 60601-2-83 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 ***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, the subject device was found to have a safety and effectiveness profile that is similar to the predicate device.

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 subject device Light Based Hair Removal Device is to be concluded substantial equivalent to its predicate device.