July 7, 2022

Shenzhen Semlamp Intelligent Technology Co., Ltd
℅ Cassie Lee
Manger
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510530
China

Re: K221246
Trade/Device Name: IPL Hair Removal (Model: SL-B080, SL-B126, SL-B136)
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: April 20, 2022
Received: May 2, 2022

Dear Cassie Lee:

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,

Jianting Wang
Acting 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)*
K221246

Device Name
IPL Hair Removal (Model: SL-B080, SL-B126, SL-B136)

Indications for Use *(Describe)*
The IPL Hair Removal 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.

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510(k) Summary for K221246

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 878.4810.

1. Submitter's Information

Company Name: Shenzhen Semlamp Intelligent Technology Co., Ltd
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Application Correspondent:
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Guangzhou GLOMED Biological Technology Co., Ltd.
Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Date of the summary prepared: July 6, 2022

3. Subject Device Information

Classification Name: Light Based Over-The-Counter Hair Removal
Trade Name: IPL Hair Removal
Model Name: SL-B080, SL-B126, SL-B136
Review Panel: General & Plastic Surgery
Product Code: OHT
Regulation Number: 21 CFR 878.4810
Regulatory Class: II

4. Predicate Device Information

Predicate Device 1 (Primary Predicate Device)
Sponsor: Shenzhen Bosidin Technology Co., Ltd.
Trade Name: IPL Home Use Hair Removal Device, model: D-1128, D-1103, D-1119, D-1129, D-1130

Classification Name: Light Based Over-The-Counter Hair Removal
510(K) Number: K192432
Review Panel: General & Plastic Surgery
Product Code: OHT
Regulation Number: 21 CFR 878.4810
Regulation Class: 2

Predicate Device 2 (Secondary Predicate Device)
Sponsor: Shenzhen Mismon Technology Co., Ltd.
Trade Name: Home Use IPL Beauty Device
Model(s): MS-208B, MS-212B, MS-216B, MS-218B, MELSYA-M6, MELSYA-M7
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
510(K) Number: K210311
Review Panel: General & Plastic Surgery
Product Code: OHT
Regulation Number: 21 CFR 878.4810
Regulation Class: 2

5. 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 IPL technology. The device provides hair reduction using Intense Pulsed Light (IPL) technology. 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 mainly contains a Xenon lamp 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), the device cannot emit the treatment light pulses. The device is for single-person use only.

The IPL Hair Removal includes SL-B080, SL-B126, and SL-B136 three models. The difference of all models is mainly the exception of appearance and number of buttons which do not affect the intended use. For model SL-B080, it consists of an IPL beauty device main body and power adapter two parts, and one non-removable lamp head (light-emitting treatment window) located in the main body which is the source of optical radiation, namely a Xenon flashlamp. In addition, the device is equipped with a manual shaver, sunglasses and replacement lampshade in addition to the IPL beauty device main body and adapter.
The user can control the device effectively by the buttons on the main unit. There are 2 operation buttons: Power button (turning on/off the device and selecting the level of gears) and Mode/Flash button.

For model SL-B126 and SL-B136, consisting of IPL beauty device main body and power adapter two parts, and one non-removable lamp head (light-emitting treatment window) located in the main body which is the source of optical radiation, namely a Xenon flashlamp. In addition, the device is equipped with a manual shaver and sunglasses in addition to the IPL beauty device main body and adapter.
The user can control the device effectively by the buttons on the main unit. There are 3 operation buttons: Power button (turning on/off the device), Auto/Manual button and Flash button.

6. Intended Use / Indications for Use

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

7. Test Summary

IPL Hair Removal (Model: SL-B080, SL-B126, SL-B136) has been evaluated the safety and performance by lab bench testing as following:

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the IPL Home Use 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 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 –Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010/(R)2014, Biological Evaluation of Medical Devices –Part 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

➢ IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

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.

8. Comparison to predicate device and conclusion

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1 (Primary Predicate Device)	Predicate Device 2 (Secondary Predicate Device)	Remark
Company	Shenzhen Semlamp Intelligent Technology Co., Ltd	Shenzhen Bosidin Technology Co.,Ltd.	Shenzhen Mismon Technology Co., Ltd.	--
Trade Name	IPL Hair Removal, Model: SL-B080, SL-B126, SL-B136	IPL Home Use Hair Removal Device	Home Use IPL Beauty Device, model: MS-208B, MS-212B, MS-216B, MS-218B, MELSYA-M6, MELSYA-M7	--
Classification Name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	--
510(k) Number	K221246	K192432	K210311	--
Product Code	OHT	OHT	OHT	Same
Intended Use /	The IPL Hair Removal is	IPL Home Use Hair	The Home Use IPL	Same

Elements of Comparison	Subject Device	Predicate Device 1 (Primary Predicate Device)	Predicate Device 2 (Secondary Predicate Device)	Remark
Indications for Use	an over the-counter device intended for removal of unwanted body and/or facial hair.	Removal Device is an over the-counter device intended for removal of unwanted body and/or facial hair.	Beauty Device 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.	
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelength Range	510-1100nm	Regular window: 510nm-1100nm Filter window: 600-1100nm	Not publicly available	Same
Pulse duration	9-12 milliseconds	7.5~14ms	9-12 milliseconds	Same
Energy density	2.2-4.0J/cm²	2.0~4.0J/cm² (applicable for model D-1128, D1119, D-1129, D1130) 2.5~4.5J/cm² (applicable for model D-1103)	2.6~5.1J/cm²	Similar Note
Spot size (size of treatment window)	3.0cm²	Regular window: 4.5cm², 2.0cm², 3.0cm² Filter window: 2.5cm²	MS208B/MS212B/MELSYAM6: 3.6cm² MS-216B/MS218B/MELSYA-M7: 3.0cm²	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Pulsing control	Finger switch	Finger switch	Finger switch	Same
Location for use	OTC	OTC	OTC	Same

Elements of Comparison	Subject Device	Predicate Device 1 (Primary Predicate Device)	Predicate Device 2 (Secondary Predicate Device)	Remark
Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471 IEC 60601-1-6	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IE C60601-1-11 IEC 60601-2-57 IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Note:

Although the “Energy density” is a similar from the predicate devices, but the value of the predicate device can override the value of the subject device, also they all complied with the IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57 and IEC 62471 safety standards’ requirements. So, these slight differences will not raise any safety or effectiveness issue.

Final Conclusion:

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device K192432 and K210311.