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

Re: K240969
Trade/Device Name: IPL Hair Removal (SL-B287, SL-B329, SL-B301-1, SL-B328)
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: March 27, 2024
Received: April 9, 2024

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 (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,

for Yan Fu -S

Digitally signed by Yan Fu -S
Date: 2024.05.31 09:10:04 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240969

Device Name
IPL Hair Removal (SL-B287, SL-B329, SLB301-1, SL-B328)

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.

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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510(k) Summary of K240969

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Company Name: Shenzhen Semlamp Intelligent Technology Co., Ltd
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Application Correspondent:

Contact Person: Ms. Cassie Lee
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. Subject Device Information:

Classification Name: Light Based Over-The-Counter Hair Removal
Trade Name: IPL Hair Removal
Model Name: SL-B287, SL-B329, SL-B301-1, SL-B328
Review Panel: General & Plastic Surgery
Product Code: OHT
Regulation Number: 21 CFR 878.4810
Regulatory Class: II

3. Predicate Device Information

Primary Predicate Device

Sponsor: Shenzhen Lescolton Electrical Appliance Co., Ltd.
Trade Name: IPL Hair Removal Device (LS-T106, LS-T107, LS-T108)
Classification Name: Light Based Over-The-Counter Hair Removal
510(K) Number: K232499
Review Panel: General & Plastic Surgery
Product Code: OHT
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Reference Device

Sponsor: Shenzhen Wochuan Electronic Co., Ltd
Trade Name: IPL Hair Removal, Model: W-1095, W-1098
Classification Name: Light Based Over-The-Counter Hair Removal
510(K) Number: K232124
Review Panel: General & Plastic Surgery
Product Code: OHT
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. 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. 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.
For model SL-B287 and SL-B329, they consist of IPL beauty device main body and power adapter (12V3A) 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 sunglass.
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, select light intensity level), Flash button (to start flashing) and Ice Cooling button (to select ice cooling mode and switch manual / auto flash mode).
For model SL-B301-1 and SL-B328, consisting of an IPL beauty device main body and power adapter (12V2A) 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, sunglass and replacement lampshade.
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.

5. 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.

6. Comparison to predicate devices

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

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device	Remark
Company	Shenzhen Semlamp Intelligent Technology Co., Ltd	Shenzhen Lescolton Electrical Appliance Co., Ltd.	Shenzhen Wochuan Electronic Co., Ltd	--
Trade Name	IPL Hair Removal, Model: SL-B287, SL-B329, SL-B301-1, SL-B328	IPL Hair Removal Device (LS-T106, LS-T107, LS-T108)	IPL Hair Removal, Model W-1095, W-1098	--
Classification Name	Light Based Over-The-Counter Hair Removal	Light Based Over-The-Counter Hair Removal	Light Based Over-The-Counter Hair Removal	--
510(k) Number	K240969	K232499	K232124	--
Product Code	OHT	OHT	OHT	Same
Class	II	II	II	Sames
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.	The IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/ or facial hair	IPL Hair Removal is an over-the-counter device intended for removal of unwanted body and/or facial hair.	Same
Prescription or OTC	OTC	OTC	OTC	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc Flashlamp	Xenon Arc	Xenon Arc Flashlamp	Same

		Flashlamp		
Wavelength Range	470nm-1200nm	LS-T106: 610-1200nm LS-T107: 560-1200nm LS-T108: 470-1200nm	470nm-1100nm	Same
Pulse duration	9-12 milliseconds	LS-T106: 0.64-2.4ms LS-T107: 7.2-10.8ms LS-T108: 6.8-10.2ms	4-13ms	Similar Note 1
Energy density	SL-B287: 2.2-5.3J/cm² SL-B329: 2.2-5.3J/cm² SL-B301-1: 1.9-3.4J/cm² SL-B328: 1.9-3.4J/cm²	LS-T106: 2.0-4.87J/cm2 LS-T107: 2.16-5.18J/cm2 LS-T108: 2.0-5.62J/cm2	W-1095:1.67~4.46J/cm2 W-1098:1.16~2.79J/cm2	Similar Note 1
Spot size (size of treatment window)	SL-B287: 3.6 cm² SL-B329: 3.6 cm² SL-B301-1:4.2 cm²/2 cm² SL-B328: 4.2 cm²/2 cm²	LS-T106: 3.2 cm2 LS-T107: 3.7 cm2 LS-T108: 3.2 cm2	W-1095: 2.69cm2 W-1098: 4.3cm2	Similar Note 2
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	large areas (e.g. arms, legs) and small areas (e.g. lip)	Multiple hair removal areas, including small areas (e.g. armpit, bikini lines) and large areas (e.g. arms, legs)	Face, lips, underarms, bilini lines, arms, legs, etc	Same
Safety and EMC	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 60601-1-11 IEC 60601-2-83 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Comparison in Detail(s):

Note 1:

Although the “Pulse duration” and “Energy density” of the subject device is slightly different from that of the predicate device, the values of the pulse duration and energy density of the subject device are within the range of the reference device. So, this difference will not raise any safety or effectiveness issue.

Note 2:

Although the “Spot size (size of treatment window)” of subject device is a little different from the predicate device, the difference in treatment window size is due to different designs. So, we believe that these differences will not affect the device's performance.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-11 Edition 2.1 2020-07 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 Edition 1.0 2011-01 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.
- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.

2) Biocompatibility Test

The subject device is biocompatible for its intended use. They are complied with biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Sensitization and Skin Irritation).

3) Software verification and validation

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Usability validation

Usability testing was conducted on the IPL Hair Removal, Model: SL-B287, SL-B329, SL-B301-1, SL-B328, which complies with IEC 62366-1 and IEC 60601-1-6.

7.2 Summary of Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

8. Date of the summary prepared: May 7, 2024

9. <u>Final Conclusion</u>

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device K232499 and K232124.