April 21, 2026

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

Re: K260518
Trade/Device Name: IPL Hair Removal (SL-B301, SL-B300, SL-B330, SL-B330-1, SL-B287-1, SL-B371, SL-B371-2, SL-B371-1, SL-B352, SL-B352-1, SL-B352-2, SL-B330-F)
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: February 14, 2026
Received: February 17, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Hithe
Digitally signed by Tanisha Hithe
Date: 2026.04.21 17:28:59 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260518

Device Name
IPL Hair Removal (SL-B301, SL-B300, SL-B330, SL-B330-1, SL-B287-1, SL-B371, SL-B371-2, SL-B371-1, SL-B352, SL-B352-1, SL-B352-2, SL-B330-F)

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.

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 of K260518

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
Address: Room 2017-20, Shenbaomao Building, Minqiang Community, Minzhi Street, Longhua District, Shenzhen, Guangdong, 518131 CHINA
Contact Person (including title): Qi Wenjun (CEO)
Tel: +86 13428733261
Fax: +86 0755-23490305
Post code: 518131
E-mail: info@semlamp.com

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
Common Name: Light Based Over The Counter Hair Removal Device
Trade Name: IPL Hair Removal
Model Name: SL-B301, SL-B300, SL-B330, SL-B330-1, SL-B287-1, SL-B371, SL-B371-2, SL-B371-1, SL-B352, SL-B352-1, SL-B352-2, SL-B330-F
Review Panel: General & Plastic Surgery
Product Code: OHT
Regulation Number: 21 CFR 878.4810
Regulatory Class: II

3. Predicate Device Information

Predicate Device
Sponsor: Shenzhen Jianchao Intelligent Technology Co., Ltd.
Trade Name: Hair Removal Device
Model Name: R3C16-P, R3C16-W, R3C16-G, R3C16-P Pro, R3C16-W Pro, R3C16-G Pro, R3505-W, R3505-B, R3505-W Pro, R3505-B Pro
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Common Name: Light Based Over The Counter Hair Removal Device
510(k) Number: K242710
Review Panel: General & Plastic Surgery
Product Code: OHT
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Reference Device 1
Sponsor: Shenzhen Semlamp Intelligent Technology Co., Ltd
Trade Name: IPL Hair Removal
Model Name: SL-B287, SL-B329, SL-B301-1, SL-B328
Classification Name: Light Based Over-The-Counter Hair Removal

510(k) Number: K240969
Review Panel: General & Plastic Surgery
Product Code: OHT
Regulation Number: 21 CFR 878.4810
Regulatory Class: II

Reference Device 2
Sponsor: Shenzhen Ulike Smart Electronics Co.,Ltd.
Trade Name: Ice Cooling IPL Hair Removal Device
Model Name: UIM20 GR, UIM20 BK, UIM20 SL, UIM20 CB, UIM20 WR
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Common Name: Light Based Over The Counter Hair Removal Device
510(k) Number: K242039
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.
The main differences among models are as follows:

Model Group	Power Adapter	Accessories (besides main unit & adapter)	Number of Buttons & Key Functions
SL-B301, SL-B300	12V2A	Manual shaver, **replacement head**, sunglasses, pouch.	**2 Buttons**: • Power button (On/Off & select level), • Mode/Flash button.
SL-B330, SL-B330-1, SL-B287-1, SL-B371, SL-B371-1, SL-B371-2	12V3A	**All include**: Manual shaver, sunglasses, pouch. **Except SL-B330 and SL-B371**, other models include replacement head.	**3 Buttons**: • Power button (On/Off & select light intensity), • Flash button (start flash), • Ice Cooling button (select cooling mode / switch manual/auto flash).
SL-B352	24V2A	Manual shaver, **replacement head**, sunglasses, pouch.	**3 Buttons**: • Power button (On/Off & select level), • SHR Button (short press: On/Off SHR mode, • **long press: On/Off ice cooling**),

Model Group	Power Adapter	Accessories (besides main unit & adapter)	Number of Buttons & Key Functions
			• Mode/Flash button.
SL-B352-1, SL-B352-2	24V2A	Manual shaver, sunglasses, pouch. (**No replacement head**).	**3 Buttons**: • Power button (On/Off & select level), • SHR Button (short press: On/Off SHR mode, **long press: On/Off skin tone sensor**), • Mode/Flash button.
SL-B330-F	24V2A	Manual shaver, **replacement head**, sunglasses, pouch.	**3 Buttons**: • Power button (On/Off & select light intensity), • Flash button (start flash), • Ice Cooling button (select cooling mode / switch manual/auto flash).

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, reference device does not raise new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Remark
Company	Shenzhen Semlamp Intelligent Technology Co., Ltd	Shenzhen Jianchao Intelligent Technology Co., Ltd.	Shenzhen Semlamp Intelligent Technology Co., Ltd	Shenzhen Ulike Smart Electronics Co.,Ltd	--
Trade Name	IPL Hair Removal (Models: SL-B301, SL-B300, SL-B330, SL-B330-1, SL-B287-1, SL-B371, SL-B371-2, SL-B371-1, SL-B352, SL-B352-1, SL-B352-2, SL-B330-F)	Hair Removal Device	IPL Hair Removal, Model: SL-B287, SL-B329, SL-B301-1, SL-B328	Ice Cooling IPL Hair Removal Device	--
510(k) Number	K260518	K242710	K240969	K242039	--
Product Code	OHT	OHT	OHT	OHT	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
FDA Device Classification	Class II	Class II	Class II	Class II	Same
Intended use/ Indication for Use	The IPL Hair Removal is an over the-counter device intended for removal of unwanted body and/or facial hair.	Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair.	The IPL Hair Removal is an over the-counter device intended for removal of unwanted body and/or facial hair.	Ice Cooling IPL Hair Removal Device with sapphire treatment window is indicated for the removal of unwanted hair. The device is also indicated for the	Same

Elements of Comparison	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Remark
				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.	
Environment of Use	OTC	OTC	OTC	OTC	Same
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelengths	530-1200nm	530nm-1200nm	470nm-1200nm	550-1200mm	Same
Spot size	SL-B330, SL-B371: 3.6cm²; SL-B330-1, SL-B287-1, SL-B330-F: 3.6cm² / 2.8cm²; SL-B371-1: 3.6cm²/ 2.4cm²; SL-B371-2: 3.6cm²/ 2.4cm²/ 1.8cm²; SL-B352:	R3C16-P,R3C16-W,R3C16-G: 3.2±0.25cm²; R3C16-PPro,R3C16-WPr-o,R3C16-GPro: 3.6±0.25cm²; R3505-W, R3505-B: 2.8±0.25cm²; R3505-WPro,R3505-BPro: 3.3±0.25cm²	SL-B287:3.6cm² SL-B329:3.6cm² SL-B301-1: 4.2cm²/2cm² SL-B328: 4.2cm²/2cm²	3.9cm²	Similar Note 1

Elements of Comparison	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Remark
	3.9 cm²/2.0cm²; SL-B352-2, SL-B352-1: 3.9 cm²; SL-B301, SL-B300: 4.2cm²/2cm²				
Pulse duration	SL-B352, SL-B352-1, SL-B352-2: 0.7-3.6ms; SL-B301, SL-B300, SL-B330, SL-B330-1, SL-B287-1, SL-B371, SL-B371-2, SL-B371-1, SL-B330-F: 9-12ms	R3C16series: 6-11ms R3505series: 11~12ms	9-12milliseconds	0.93ms~3.50ms Single pulse Double pulse Triple pulse	Similar Note 2
Energy density	SL-B330, SL-B371, SL-B371-1, SL-B371-2, SL-B287-1, SL-B330-1: 2.2-5.3J/cm²; SL-B352, SL-B352-2, SL-B352-1: 1.8-6.1J/cm²; SL-B330-F: 1.6-5.3J/cm²;	R3C16-P, R3C16-W, R3C16-G: 1.56J/cm^2~4.69J/cm^2 ; R3C16-PPro, R3C16-WPro, R3C16-G Pro: 1.39J/cm^2~4.17J/cm^2 ; R3505-W, R3505-B: 3.57J/cm2~7.5J/cm^2;	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	2.79J/cm^2~6.41J/cm^2	Similar Note 3

Elements of Comparison	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Remark
	SL-B301, SL-B300: 1.9-3.4J/ cm²	R3505-WPro, R3505-BPro: 3.03J/cm^2~6.36J/cm^2			
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Sterilization	Not required	Not required	Not required	Not required	Same
Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 IEC 60601-1-6	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 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 60601-1-11 IEC 60601-2-57 IEC 60601-2-83 IEC 62471	Same

Comparison in Detail(s):

Note 1:

Although the **"Spot size"** of the subject device is slightly different from that of the predicate device, the difference in treatment window size is due to different designs. Therefore, this difference will not raise any safety or effectiveness issue.

Note 2:

Although the subject device has minor differences in **"Pulse duration"** compared with the predicate device, such differences fall within the pre-validated safe and effective parameter range of the predicate device. Among them, the pulse durations of SL-B301, SL-B300, SL-B330, SL-B330-1, SL-B287-1, SL-B371, SL-B371-2, SL-B371-1, and SL-B330-F are within the range of the Predicate Device and consistent with Reference Device 1.the pulse duration of SL-B352, SL-B352-1 and SL-B352-2 is similar to that of reference device 2. In addition, the subject device complies with IEC 60601-2-83 and IEC 62471 requirement, so this difference will not raise any safety or effectiveness issue. Therefore, this difference will not raise any safety or effectiveness issue.

Note 3:

Although the **"Energy density"** of the subject device is slightly different from that of the predicate device, the values of the energy density of the subject device are within the range of the predicate device and reference device 1. In addition, the subject device complies with IEC 60601-2-83 and IEC 62471 requirement, so this difference will not raise any safety or effectiveness issue. Therefore, this difference will not raise any safety or effectiveness issue.

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:

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 60601-1-2 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 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.
- IEC60601-2-83: 2022, Medical electrical equipment- Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.
- IEC60601-1-6: 2020, Medical electrical equipment- Part 1-6: General requirements for basic safety and essential performance- Collateral standard: Usability

2) 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 Basic Documentation Level, 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.

3) Cybersecurity

Not applicable. This device is not designed to have any network connection capabilities, including wired (such as Ethernet) and wireless (such as Wi-Fi, Bluetooth, cellular network) transmission interfaces. Due to its physical isolation feature, this device cannot be connected to the hospital network, the Internet or other external systems, and thus does not pose risks related to network security, such as unauthorized data access, malware infection or service interruption. According to the FDA's cybersecurity guidelines, such connectionless devices typically do not require the implementation of specific cybersecurity control measures.

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: March 25, 2026

9. Final Conclusion

The subject device is as safe and effective, as the legally marketed predicated device K242710.