October 11, 2023

Shenzhen Lescolton Electrical Appliance Co., Ltd.
% Gong Youshan
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K232499
Trade/Device Name: IPL Hair Removal Device (LS-T106, LS-T107, LS-T108)
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: August 16, 2023
Received: August 17, 2023

Dear Gong Youshan:

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,

Jianting Wang -S

Digitally signed by Jianting Wang -S
Date: 2023.10.11 12:08:29 -04'00'

For Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices

OHT4: Office of Surgical & 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)*
K232499

Device Name
IPL Hair Removal Device

Indications for Use *(Describe)*
The IPL Hair Removal Device 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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K232499 510(k) Summary

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

Date Prepared: 2023-09-29

I. Submitter

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II. Device

Name of Device: IPL Hair Removal Device
Model(s): LS-T106, LS-T107,LS-T108
Common or Usual Name: Light Based Over-The-Counter Hair Removal
Regulation 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 and Reference Device

- **Predicate Device**

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Jizhimei Technology Co., Ltd.	IPL Cooling Hair Removal Device, Model(s): NBB01, NBB02	K230360	April 10, 2023

- **Reference Device1**

Manufacturer	Reference Device	510(k) Number	Approval Date
Shenzhen BSX Technology Electronics Co., Ltd.	IPL Hair Removal Device, Model(s): BSXT101, BSXT102, BSXT103, BSXT105, BSXT106, BSXT108	K230097	April 6, 2023

- **Reference Device2**

Manufacturer	Reference Device	510(k) Number	Approval Date
Shenzhen IONKA Medical Technology Co., Ltd.	Hand-held IPL device (IPL Home Use Hair Removal Device), Model: FZ-608, FZ-608G, FZ-100, FZ-200	K230739	May 26, 2023

- **Reference Device3**

Manufacturer	Reference Device	510(k) Number	Approval Date
Shenzhen GSD Tech Co., Ltd.	Light Based Hair Removal Device GP592	K230060	March 3, 2023

- **Reference Device4**

Manufacturer	Reference Device	510(k) Number	Approval Date
Shenzhen Yuwei Electronic Technology Co., Ltd.	IPL Hair Removal Device	K220222	April 26, 2022

IV. Device Description

IPL Hair Removal Device, is an over-the-counter, home-use device for unwanted hair reduction by using Intense Pulsed Light (IPL), and it has been designed three models with the same IPL technology for hair removal, which is model LS-T106, LS-T107 and LS-T108. The device 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 IPL Hair Removal Device has an irreplaceable light exit and it can cover an area of 3.2cm2 of LS-T106 and LS-T108, 3.7cm2 of LS-T107 that is suitable for multiple hair removal areas, such as face, lips, underarms, bikini lines, arms, legs, etc.

The device contains a skin sensor to detect appropriate skin contact, if the light exit is not in full contact with the skin, the device cannot emit the treatment light pulses. Besides, the IPL Hair Removal Device has the cooling function, which will be activated throughout the whole hair removal process to cool down the treatment area’s temperature and provide the user with a better using experience.

V. Indications for Use

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

VI. Materials

Model	Contacted Component Name	Materials

LS-T106, LS-T107	Host of machine (including air outlet, treatment window, air inlet, buttons)	PC+ABS
LS-T108	Host of machine (including air outlet, treatment window, air inlet, buttons)	PC+ABS
	Sapphire cold head (within treatment window)	AL_2O_3

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to Section "013_Biocompatibility evaluation report of IPL Hair Removal Device"

VII. Comparison of Technological Characteristics With the Predicate Device

The IPL Hair Removal Device has the same intended use as the predicate. The technological characteristics such as wavelength, energy density, spot size and pulse duration, are similar to the predicate device and reference devices. Any minor differences between the subject device and the listed predicate device and reference 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 and reference devices for its intended use.
Therefore, the IPL Hair Removal Device may be found substantially equivalent to its predicate device and reference devices.

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Reference Device 3**	**Reference Device 4**	**Remark**
510(k) Number	K232499	K230360	K230097	K230739	K230060	K220222	/
Trade name	IPL Hair Removal Device	IPL Cooling Hair Removal Device	IPL Hair Removal Device	Hand-held IPL device (IPL Home Use Hair Removal Device)	Light Based Hair Removal Device GP592	IPL Hair Removal Device	/
Manufacturer	Shenzhen Lescolton Electrical Appliance Co., Ltd	Shenzhen Jizhimei Technology Co., Ltd.	Shenzhen BSX Technology Electronics Co.,	Shenzhen IONKA Medical Technology Co., Ltd.	Shenzhen GSD Tech Co., Ltd.	Shenzhen Yuwei Electronic	/

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Reference Device 3**	**Reference Device 4**	**Remark**
			Ltd.			Technology Co., Ltd.	
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT	OHT	OHT	OHT	OHT	OHT	Same
Device classification	Class II	Class II	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	The IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/ or facial hair.	The IPL Cooling Hair Removal Device 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 Home Use Hair Removal Device is indicated for the removal of unwanted hair. The device 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.	Light based hair removal 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, excluding patients with Fitzpatrick Skin Phototypes VI.	The IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair.	Same

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Reference Device 3**	**Reference Device 4**	**Remark**
Prescription or OTC	OTC	OTC	OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick skin types I-V	Fitzpatrick skin types I-V	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Not publicly available	Same
Dimension	LS-T106: 202.3±0.8*38*56.2 mm LS-T107: 211.5*63.5*48.9 mm LS-T108: 177.5*67*40 mm	NBB01: 47.6*54.3*240 mm NBB02-MAX: 235*76*43 mm	190 x 70 x 45 mm	FZ-608, FZ-608G: 98*147*60(mm) FZ-100: 198*71*44(mm) FZ-200: 216*68*52(mm)	Not publicly available	Not publicly available	Different **Note 1**
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp	Xenon Arc lamp	Xenon Arc lamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelength range	LS-T106: 610-1200nm LS-T107: 560-1200nm LS-T108: 470-1200nm	550-1200mm	470nm-1200nm	510nm~1200nm	Not publicly available	610-1100nm	Similar, the wavelength range of LS-T106 is within reference device 1, and the min wavelength (610nm) of LS-T106 is identical to reference device 4. **Note 2**

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Reference Device 3**	**Reference Device 4**	**Remark**
Energy density	LS-T106: 2.0-4.87J/cm^2 LS-T107: 2.16-5.18J/cm^2 LS-T108: 2.0-5.62J/cm^2	2~5J/cm^2 (applicable for model NBB01) 2~4J/cm^2 (applicable for model NBB02)	Max 5.0 J/cm^2	FZ-608, FZ-608G: 3.33 J/cm2 FZ-100: 5.43 J/cm2 FZ-200: 4.5 J/cm2	4.93J/cm2 Max	2.2~5.6 J/cm^2	Similar, the energy density of LS-T106 is within predicate device of model NBB01, and the min energy density of LS-T106 is similar to reference device 4, the max energy density of LS-T106 is within reference device 4. **Note 3**
Output energy	LS-T106: 8/10/13J (±20%) LS-T107: 10/13/16J (±20%) LS-T108: 8/12/15J (±20%)	Model NBB01: 8 ~ 17.05J Model NBB02: 7.14 ~ 13.62J	Pure mode: 5~10J (±20%) Armpit mode: 6~10J (±20%) Body mode: 6.5~11J (±20%) Bikini mode: 8~12.5J (±20%)	FZ-608, FZ-608G: Level 1: 4.16J Level 2: 4.36J Level 3: 5.1J Level 4: 6.1J Level 5: 6.96J Level 6: 7.96J Level 7: 8.63J Level 8: 9.13J	Not publicly available	Level 1: 8.82J (±20%) Level 2: 10.09J (±20%) Level 3: 12.73J (±20%) Level 4: 14.24J (±20%)	Similar, consider the error ± 20%, the min output energy of LS-T106 is 6.4J which is within reference

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Reference Device 3**	**Reference Device 4**	**Remark**
				Level 9: 10.0J		Level 5: 16.76J (±20%)	device 1 of armpit mode; the max output energy of LS-T106 is 15.6J which is within predicate device of model NBB01. Also, the output energy is within reference device 4. **Note 3**
Spot size	LS-T106: 3.2 cm^2 LS-T107: 3.7 cm^2 LS-T108: 3.2 cm^2	3.6cm^2 (applicable for model NBB01 and NBB02)	3.0cm^2± 0.5cm^2	3.0cm^2	1.05cm*2.95cm (3.1cm^2)	3.0cm^2, 4.1cm^2	Similar, the spot size of LS-T106 is similar to reference device 1, 2, 3 and 4. **Note 4**
Pulse duration	LS-T106: 0.64-2.4ms LS-T107: 7.2-10.8ms LS-T108: 6.8-10.2ms	6.4-7.2ms	4-10ms	0.5~0.8 ms	1~3 ms	8~14ms	Similar, the min pulse duration of LS-T106 is

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Reference Device 3**	**Reference Device 4**	**Remark**
							0.64ms which is within reference device 2, the max pulse duration of LS-T106 is 2.4ms which is within reference device 3. **Note 5**
Output intensity level	LS-T106: 3 levels LS-T107: 3 levels LS-T108: 3 levels	NBB01: 5 levels NBB02: 6 levels	5 Levels	FZ-608, FZ-608G: 9 levels FZ-100: 9 levels FZ-200: 6 levels	Not publicly available	1~5 levels	Different **Note 6**
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Yes	Same
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	Same
Eye safety	IEC 62471	IEC 62471	IEC 62471	IEC 62471	IEC 62471	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Comparison Elements	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Reference Device 4	Remark
					ISO 10993-23		

Note 1:
Though the dimension is different from the predicate device and reference device, this difference is insignificant and do not raise any safety or effectiveness problems.

Note 2:
Though the wavelength of subject device is different from the predicate device, the wavelength of the subject device can be basically covered by the reference device 1's range. The wavelength range of LS-T106 is within reference device 1, and the min wavelength (610nm) of LS-T106 is identical to reference device 4, and they all comply with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Note 3:
Though the energy density and the output energy of subject device is a little different from the predicate device and reference devices, consider the error ±20%, the energy density and the output energy of subject device is within the range of the minimum and maximum value of the predicate device and reference devices.
The energy density of LS-T106 is within predicate device of model NBB01, and the min energy density of LS-T106 is similar to reference device 4, the max energy density of LS-T106 is within reference device 4.
The min output energy of LS-T106 is 6.4J which is within reference device 1 of armpit mode; the max output energy of LS-T106 is 15.6J which is within predicate device of model NBB01. Also, the output energy is within reference device 4, and they all comply with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Note 4:
There is minor difference in spot size between the subject device and the reference devices. The spot size is related to energy density while the energy density of subject device and predicate device is the same as explained in Note 3, the spot size of LS-T106 is similar to reference device 1, 2, 3 and 4, so this difference is not significant and will not raise any safety or effectiveness issue.

Note 5:
Though the pulse duration of subject device is different from the predicate device, the range of LS-T107, LS-T108 is within reference device 1. The min pulse duration of LS-T106 is 0.64ms which is within reference device 2, the max pulse duration of LS-T106 is 2.4ms which is within reference device3. In addition, the subject device comply with IEC 60601-2-83 and IEC 62471 requirement, so this difference will not raise any safety or effectiveness issue.

Note 6:
Though the output intensity level of subject device is different from the predicate device and reference devices, the wavelength, output energy and energy density of the subject device can be basically same with predicate device and reference devices as explained in Note 3, and they all comply with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

VIII. 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 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 September 4, 2020", as recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5:2009, Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices –Part 10: Tests for skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices –Part 23: Tests for skin irritation

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, the following standards:

- ANSI AAMI ES60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 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 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.

IX. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device IPL Hair Removal Device is as safe, as effective, and performs as well as the legally marketed predicate device and reference device.