



July 9, 2024

Shenzhen Lescolton Electrical Appliance Co., Ltd
% Youshan Gong
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: K241343

Trade/Device Name: IPL Hair Removal Device (LS-T121, LS-T121A, LS-T121B, LS-T121C, LS-T130, LS-T130A, LST130B, LS-T133, LS-T135, LS-T136, LS-T137, LS-T134, LS-T138, LS-T139, LS-T140)

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: May 11, 2024

Received: May 13, 2024

Dear Youshan Gong:

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**
Tanisha Hithe

Digitally signed by Yan Fu -S
Date: 2024.07.09 09:34:36
-04'00'

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

Indications for Use

510(k) Number (if known)

K241343

Device Name

IPL Hair Removal Device Model(s): LS-T121, LS-T121A, LS-T121B, LS-T121C, LS-T130, LS-T130A, LS-T130B, LS-T133, LS-T135, LS-T136, LS-T137, LS-T134, LS-T138, LS-T139, LS-T140

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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K241343 510(k) Summary

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

Date Prepared: 2024-6-17

I. Submitter

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II. Device

Name of Device: IPL Hair Removal Device
Model(s): LS-T121, LS-T121A, LS-T121B, LS-T121C, LS-T130, LS-T130A, LS-T130B, LS-T133, LS-T135, LS-T136, LS-T137, LS-T134, LS-T138, LS-T139, LS-T140
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**

■ **For LS-T133/135/136/137, LS-T134/138/139/140**

<u>Manufacturer</u>	<u>Predicate Device</u>	<u>510(k) Number</u>
Shen Zhen CosBeauty Co., Ltd.	IPL Hair Removal Device Joy Version	K173813

■ **For LS-T121/121A/121B/121C, LS-T130/130A/130B**

<u>Manufacturer</u>	<u>Predicate Device</u>	<u>510(k) Number</u>
Shenzhen Lescolton Electrical Appliance Co., Ltd	IPL Hair Removal Device	K232499

➤ **Reference Device**

■ **For LS-T133/135/136/137, LS-T134/138/139/140**

<u>Manufacturer</u>	<u>Reference Device</u>	<u>510(k) Number</u>
Shenzhen Jizhimei Technology Co., Ltd.	IPL Cooling Hair Removal Device	K230360

■ **For LS-T121/121A/121B/121C, LS-T130/130A/130B**

<u>Manufacturer</u>	<u>Reference Device</u>	<u>510(k) Number</u>
Shenzhen IONKA Medical Technology	Hand-held IPL device (IPL Home Use Hair Removal	K230739

Manufacturer	Reference Device	510(k) Number
Co., Ltd.	Device)	

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 15 models with the same IPL technology for hair removal, which is model LS-T121/121A/121B/121C, LS-T130/130A/130B, LS-T133/135/136/137, LS-T134/138/139/140. 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.

IPL Hair Removal Device is a Pulsed Light system which emits intense pulsed light (IPL) at a wavelength ranging from 510-1200nm and 600-1200nm. The device works on the principles of selective photothermolysis. That is, causing thermal damage to target chromophores by using light of appropriate wavelength in pulses that exceeds the chromophores' thermal relaxation time but sparing normal skin by limiting the pulse width below the thermal relaxation time for skin.

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-T121/121A/121B/121C, LS-T130/130A/130B, LS-T133/135/136/137, LS-T134/138/139/140	Host of machine (including air outlet, treatment window, air inlet, buttons)	PC, ABS, PC+ABS, ADC12, Al2O3 (fineness>99.995%), PEEK+30%GF, PC2805+POM

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to Section Biocompatibility Discussion.

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 not 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.

IPL Hair Removal Device is compared with the following Predicate Devices in terms of intended use, design, material, specifications and performance:

1. For LS-T133/135/136/137, LS-T134/138/139/140

<u>Comparison Elements</u>	<u>Subject device</u>	<u>Predicate Device</u>	<u>Reference Device</u>
510(k) Number	K241343	K173813	K230360
Trade name	IPL Hair Removal Device	IPL Hair Removal Device Joy Version	IPL Cooling Hair Removal Device
Manufacturer	Shenzhen Lescolton Electrical Appliance Co., Ltd	Shen Zhen CosBeauty Co., Ltd.	Shenzhen Jizhimei Technology Co., Ltd.
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Product	OHT	OHT	OHT

<u>Comparison Elements</u>	<u>Subject device</u>	<u>Predicate Device</u>	<u>Reference Device</u>
code			
Device classification	Class II	Class II	Class II
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 Hair Removal Device Joy Version 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. The device is used for adults with Fitzpatrick skin types I – IV.	The IPL Cooling Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair.
Prescription or OTC	OTC	OTC	OTC
Wavelength range	LS-T133/135/136/137: 510-1200nm LS-T134/138/139/140: 510-1200nm	510nm~1200nm Max	550-1200mm

<u>Comparison Elements</u>	<u>Subject device</u>	<u>Predicate Device</u>	<u>Reference Device</u>
Energy density	LS-T133/135/136/137: 1.8~5J/cm ² LS-T134/138/139/140: 1.7~4.7J/cm ²	5.1 J/cm ²	2~5J/cm ² (applicable for model NBB01) 2~4J/cm ² (applicable for model NBB02)
Spot size	LS-T133/135/136/137: 5.2 cm ² LS-T134/138/139/140: 5.6 cm ²	Body: 4.2 [cm ²], Bikini area and Face: 2 [cm ²]	3.6cm ² (applicable for model NBB01 and NBB02)
Pulse duration	LS-T133/135/136/137: 9.20-11.20ms LS-T134/138/139/140: 9.20-11.20ms	9.20~11.20milliseconds	6.4-7.2ms

2. For LS-T121/121A/121B/121C, LS-T130/130A/130B

<u>Comparison Elements</u>	<u>Subject device</u>	<u>Predicate Device</u>	<u>Reference Device</u>
510(k) Number	K241343	K232499	K230739
Trade name	IPL Hair Removal Device	IPL Hair Removal Device	Hand-held IPL device (IPL Home Use Hair Removal Device)
Manufactur	Shenzhen Lescolton Electrical	Shenzhen Lescolton	Shenzhen IONKA

<u>Comparison Elements</u>	<u>Subject device</u>	<u>Predicate Device</u>	<u>Reference Device</u>
Manufacturer	Appliance Co., Ltd	Electrical Appliance Co., Ltd	Medical Technology Co., Ltd.
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Product code	OHT	OHT	OHT
Device classification	Class II	Class II	Class II
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 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.

<u>Comparison Elements</u>	<u>Subject device</u>	<u>Predicate Device</u>	<u>Reference Device</u>
Prescription or OTC	OTC	OTC	OTC
Wavelength range	LS-T121: 600-1200nm LS-T130: 600-1200nm	LS-T106: 610-1200nm LS-T107: 560-1200nm LS-T108: 470-1200nm	510nm~1200nm
Energy density	LS-T121: 2.5-6.0J/cm ² LS-T130: 1.3~5.7 J/cm ²	LS-T106: 2.0-4.87J/cm ² LS-T107: 2.16-5.18J/cm ² LS-T108: 2.0-5.62J/cm ²	FZ-608, FZ-608G: 3.33 J/cm ² FZ-100: 5.43 J/cm ² FZ-200: 4.5 J/cm ²
Spot size	LS-T121: 3.2 cm ² LS-T130: 3.6 cm ²	LS-T106: 3.2 cm ² LS-T107: 3.7 cm ² LS-T108: 3.2 cm ²	3.0cm ²
Pulse duration	LS-T121: 9-12ms LS-T130: 0.5-5ms	LS-T106: 0.64-2.4ms LS-T107: 7.2-10.8ms LS-T108: 6.8-10.2ms	0.5~0.8 ms

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 subject 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”, 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:

- IEC 60601-1:2005/AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11:2015+A1:2020 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 60601-2-83:2019 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

3) Eye Safety

- IEC 62471:2006 Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with *basic documentation level* 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.