September 28, 2023

Lumenessa Corp
% Xuexia Ren
Director Chengdu Office
Delta Technology Service (Shenzhen) Co., Ltd.
1-01, Building 1&1-01 A-01, Building3, No.15 Jinhui Rd.
Kengzi Subdistrict, Pingshan District
Shenzhen, 518118
China

Re: K232274
Trade/Device Name: IPL hair removal device
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: July 28, 2023
Received: July 31, 2023

Dear Xuexia Ren:

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2023.09.28
10:57:51 -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)*
K232274

Device Name
IPL hair removal device

Indications for Use *(Describe)*
The product is an over-the-counter device intended for removal of unwanted body and 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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Chapter 6. 510(k) Summary

510(k) Summary
K232274

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

- 510(k) Owner's Name: Lumenessa Corp
- Establishment Registration Number: Applying
- Address: 10606 Shoemaker Ave #A, Santa Fe Springs, CA 90670
- Tel: 1-408-5623072121
- Fax: /
- Contact Person: Peter Kim (Vice President)
- Email: peter@lumenessa.com
- Date Prepared: September 26, 2023

Application Correspondent:

- Contact Person: Ms. Ren Xuexia
- Delta Technology Service(Shenzhen) Co., Ltd.
- Address: 1-01, Building 1&1-01 A-01, Building3, No.15 Jinhui Rd., Kengzi Subdistrict, Pingshan District, Shenzhen, 518118, China
- Tel: +86-18030755441
- Email: renxuexia@deltates.com

2. Subject Device Information

- Common Name: Light Based Over-The-Counter Hair Removal
- Trade Name: IPL hair removal device (Model: LS101, LS102)
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Review Panel: General & Plastic Surgery
- Product Code: OHT
- Regulation Number: 878.4810
- Regulation Class: II

3. Predicate Device Information

Predicate Device 1 Information

- Common Name: Light based over the counter hair removal system
- 510(k) Number: K160968
- Sponsor: CyDen Limited.
- Trade Name: iPulse SmoothSkin Gold Hair Removal Device
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

- Review Panel: General & Plastic Surgery
- Product Code: OHT, GEX
- Regulation Number: 878.4810
- Regulation Class: II

Predicate Device 2 Information

- Common Name: Light Based Over-The-Counter Hair Removal
- 510(k) Number: K161428
- Sponsor: Shen Zhen CosBeauty Co., Ltd
- Trade Name: PerfectSmooth
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Review Panel: General & Plastic Surgery
- Product Code: OHT
- Regulation Number: 878.4810
- Regulation Class: II

4. Device Description

IPL hair removal device 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 contains a Xenon lamp and a skin tone 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 be triggered a pulse emitting.

The IPL hair removal device includes LS101 and LS102 two models. Their intended use, performance, structure design and operation are identical, with the different color of grip part. The difference does not affect or change the intended use of the device.

5. Intended Use / Indications for Use

The product is an over-the-counter device intended for removal of unwanted body and facial hair.

6. Test Summary

IPL hair removal device, Model: LS101, LS102 has been evaluated for the safety and performance by lab bench testing as following:

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, including:

- ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization
- ISO 10993-10:2021 Biological evaluation of medical devices-Part 10:Tests for skin sensitization

2) Electrical Safety and Eye Safety

- IEC 60601-1 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 compatibility
- 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

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.

5) OTC Usability Study

An OTC Usability Study was enrolled a total of 20 participant and was conducted to provide a basis for the Company to gather data from the layperson relative to level of labeling understanding of what the device is, what the device does and how to operate the device. This Study was completed successfully and the results were no issues or negative comments.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of IPL hair removal device (Model: LS101, LS102) is substantially equivalent to the predicate devices quoted above.
The differences between the subject device and predicate devices do not raise new question of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Device Name	IPL hair removal device Model: LS101, LS102	iPulse SmoothSkin Gold Hair Removal Device	PerfectSmooth	--
510(k) Number	K232274	K160968	K161428	--
Indications for Use	The product is an over-the-counter device intended for removal of unwanted body and facial hair.	The iPulse SmoothSkin Gold Hair Removal System is an over the counter device intended for the removal of unwanted hair.	The PerfectSmooth 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.	SE Note 1

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Wavelength range	523nm ~ 1100nm	510-1100nm	≥510nm	SE Note 2
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	SE
Energy density	3.2-6.5J/cm²	3-6J/cm^2	4.7 J/cm²	SE Note 3
Spot size	Standard care head: 3cm^2(30mm*10mm) Precision care head: 1.2cm^2(12mm*10mm)	3cm^2 (3cm by 1cm)	4.5 cm²	SE Note 2
Pulse duration	<10 ms	2ms to 10ms	11-13 ms	SE Note 4
Pulsing control	Finger switch	Finger switch	Finger switch	SE
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	SE
Location for use	OTC	OTC	OTC	SE
Biocompatibility	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10	SE
Electrical Safety	IEC 60601-1, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-11, IEC 60601-2-57	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	SE
Eye Safety	IEC 62471	IEC 62471	IEC 62471	SE

Comparison in Detail(s):

Note 1:

The “Indications for Use” of subject device is described in a different way than the predicate devices, but they show that the actual use of the device is similar, namely "removal of unwanted hair".

So the differences of description will not raise any safety or effectiveness issue.

Note 2:

Although the “Wavelength range” and “Spot size” of subject device are a little different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-2-57 requirement.

So the differences of function specification will not raise any safety or effectiveness issue.

Note 3:

Although the “Energy density” of subject device is a little different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-2-57 requirement. And the Energy density of subject device is in the range of the predicate device 1.

So the differences of function specification will not raise any safety or effectiveness issue.

Note 4:

Although the “Pulse duration” of subject device is a little different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-2-57 requirement. And the Pulse duration of subject device is almost identical to the predicate device 1.
So the differences of function specification will not raise any safety or effectiveness issue.

Summary:
The subject device "IPL hair removal device, model: LS101, LS102" is Substantial Equivalent to the predicate devices.

8. Conclusion
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the subject device "IPL hair removal device, model: LS101, LS102" is to be concluded substantial equivalent to its predicate devices.