January 12, 2024

Shenzhen Idea Light Limited
% Lee Cassie
Official Correspondent
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Huangpu District, Guangzhou, China
Guangzhou, Guangdong
China

Re: K233114
Trade/Device Name: LED silicone mask (Model: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200)
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: OHS, OLP
Dated: December 29, 2023
Received: December 29, 2023

Dear Lee Cassie:

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
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Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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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.

Submission Number *(if known)*

K233114

Device Name

LED silicone mask (Model: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200)

Indications for Use *(Describe)*

LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200) is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face.
LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200) is an over-the-counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face wrinkles.

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 K233114

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

1. Date of the summary prepared: September 26, 2023

2. Submitter's Information

Company Name: Shenzhen Idea Light Limited
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Application Correspondent:

Contact Person: Cassie Lee
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Subject Device Information

Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The-Counter Wrinkle Reduction (OHS)
Trade Name: LED silicone mask
Model Name: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810
Regulatory Class: II

3. Predicate Device Information

510(k) Number: K221775
Sponsor: Light Tree Ventures Europe B.V.
Trade Name: LED Light Therapy Mask
Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Device Description

LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200) is an over-the-counter light emitting diode (LED) device that emits energy for use in dermatology for the treatment of acne and wrinkles. The device has anti-wrinkle mode and anti-acne, the former is to emit red light (630nm) and infrared light (830nm) to treat wrinkles, the latter is to emit red light (630nm) and blue light (415nm) to treat mild to moderate acne.
This device contains Removable Eye Protection, Shell (Inner surface) and Shell (Outer surface), and a controller. Removable Eye Protection is designed to protect the user's eyes from light damage.

There are four buttons on the controller, which are setting button, left and right selection button and power button. Press the setting button, and then press the "left" or "right" button to select R/BLUE and R/NIR modes. The power button controls the device's on/off, pause and start.
There are three models of device, with only a slight difference in appearance. All wavelength, output mode and energy are same.

5. Intended Use / Indications for Use

LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200) is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face.
LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200) is an over-the-counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face wrinkles.

6. Comparison to predicate device

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

Elements of Comparison	Subject Device	Predicate Device	Remark
Company	Shenzhen Idea Light Limited	Light Tree Ventures Europe B.V.	--
Trade Name	LED silicone mask	LED Light Therapy Mask	--
Model	LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200	MK-78, MK-04, MK66-H, EL00003	--
510(k) Number	Applying	K221775	--
Product Code	OHS, OLP	OHS, OLP	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Same
FDA Device Classification	Class II	Class II	Same
Use	Over the Counter	Over the Counter	Same
Indication for Use	LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200) is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200) is an over-the-counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face wrinkles.	For MK-78, MK-04 The LED Light Therapy Mask (Models: MK-78, MK-04) is an over the counter device that is intended for the use in the treatment of full-face wrinkles. For MK66-H, EL00003 The LED Light Therapy Mask (Models: MK66-H, EL00003) is an over the counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. The LED Light Therapy Mask (Models: MK66-H, EL00003) is an over the counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face wrinkles	Same
Intended Location of Use	Face	Face	Same

Elements of Comparison	Subject Device	Predicate Device	Remark
Energy Type	Light emitting diodes	Light emitting diodes	Same
Wavelengths	Red: 630nm±5nm Blue: 415nm NIR: 830nm	Red: 630nm±5nm Blue: 415nm NIR: 830nm	Same
Number of LEDs	Red: 114 Blue: 114 NIR: 114	Not publicly	Different Note
Total Intensity (mw/cm^2)	Blue/Red 44 mw/cm^2	Blue/Red 44 mw/cm^2	Same
	Red/NIR 30 mw/cm^2	Red/NIR 30 mw/cm^2	
Dose	Blue/Red 26.4 J/cm^2 Red/NIR 18 J/cm^2	Blue/ Red 26.4J/cm^2 Red/ NIR 18 J/cm^2	Same
Treatment time	10 minutes/day	10 minutes	Same
Treatment protocol	Acne: 4 x weekly, 6 weeks	Acne: 4 x weekly, 6 weeks	Same
	Wrinkles: 5 x weekly, 6 weeks	Wrinkles: 5 x weekly, 6 weeks	
Software Controlled	Device uses a timer and software to control treatment duration	Device uses a timer and software to control treatment duration	Same
Power supply	Rechargeable Lithium battery	Rechargeable Lithium battery	Same

Note:
The main parameters that ultimately affect the safety and effectiveness of the device are the energy and dosage of treatment, and the light beads are evenly distributed, which does not affect the safety of the device. So even if there is a difference between the number of lamp beads and the predicate device, it is still acceptable.

7. Test Summary

8.1 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 62133-2 Edition 1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems.
- IEC /TR 60601-4-2 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

1) Biocompatibility Test
The component of the LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200) has been conformed to ISO 10993-5, ISO 10993-10 and ISO 10993-23.

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 "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.

3) Usability validation
Usability testing was conducted on the LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200), which complies with IEC 62366-1 and IEC 60601-1-6.

8.2 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. Final Conclusion:
The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K221775.