February 5, 2025

Shenzhen Eyco Technology Co., Ltd
% Lee Cassie
Official Correspondent
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road
Huangpu District, Guangzhou, China
Guangdong, Guangzhou 510530
China

Re: K243555
Trade/Device Name: LED light therapy mask (E43, E32, E49B, E49C, E100B, E100C, E103B, E104B, E106A, E108A)
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: OLP, OHS
Dated: November 15, 2024
Received: November 18, 2024

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.

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 L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.02.05 14:45:07 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243555

Device Name

LED light therapy mask (E43, E32, E49B, E49C, E100B, E100C, E103B, E104B, E106A, E108A)

Indications for Use *(Describe)*

- Mode 1 (Red + Infrared light): treatment of full face wrinkles.
- Mode 2 (Blue light): Treatment of mild to moderate inflammatory acne.
- Mode 3 (Mixed light): Treatment of mild to moderate inflammatory acne.

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.

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510(K) Summary for K243555

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

Sponsor Name: Shenzhen Eyco Technology Co., Ltd
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Application Correspondent:
Contact Name: Cassie Lee
Company: Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8200 6973
E-mail: 382198657@qq.com

2. Subject Device Information:

Trade Name: LED light therapy mask
Model: E43, E32, E49B, E49C, E100B, E100C, E103B, E104B, E106A, E108A
Medical specialty: General & Plastic Surgery
Regulation: 21 CFR 878.4810
Product Code: OLP (Class II) - Over-The-Counter Powered Light Based Laser For Acne
Associated Product Code(s): OHS (Class II) - Light Based Over The Counter Wrinkle Reduction

3. Predicate Device Information

Predicate Device 1:

Sponsor: Guangdong Newdermo Biotech Co.,Ltd
Trade Name: LED light therapy mask
510(k) Number: K223544
Medical specialty: General & Plastic Surgery
Regulation: 21 CFR 878.4810
Product Code: OLP, OHS

Predicate Device 2:

Sponsor: Marci Beauty Inc

Trade Name: Infrared Red Blue LED Light Heat Beauty Machine

510(k) Number: K210545

Medical specialty: General & Plastic Surgery

Regulation: 21 CFR 878.4810

Product Code: OLP, OHS

Reference Device:

Sponsor: Ambicare Health Ltd

Trade Name: Lustre PRO Light System

510(k) Number: K143713

Medical specialty: General & Plastic Surgery

Regulation: 21 CFR 878.4810

Product Code: OLP

4. Device Description

LED phototherapy masks are over-the-counter light-emitting diode (LED) devices that emit energy and are used in dermatology to treat acne and wrinkles. The device emits red (630nm) and infrared (850nm) light to treat wrinkles and blue (415nm) light to treat mild to moderate acne. All models had to be fitted with an eye mask and strapped to the treatment area, and all had a controller to set the parameters of the device.

There are 10 models of the device (model: E43, E32, E49B, E49C, E100B, E100C, E103B, E104B, E106A, E108A), all of which are operated through a controller. The differences between the 10 models are listed below:

1. Mode of power supply:

- For E43 and E32 devices, the device of model E43, E32 are powered by connecting to the mains, connected to the controller through the adapter, and then connected to the mask through the power cord provided by the manufacturer.
- For masks E49B, E49C, E100B, E100C, E103B, E104B, E106A, E108A, power the device and control the operation through the lithium battery inside the controller (Specifications adapter can be used (input AC100-240V 50/60Hz, outputs DC 10V 2A) to charge the controller).

2. Different manufacturing materials: E32 and E43 are hard cases, and the material is PC. The corresponding equipment of E49B, E49C, E100B, E100C, E103B, E104B, E106A and E108A are soft cases, and the material is silica gel.

3. The controller is different, the device model (E43, E32) has 4 LED lights, 7 buttons and LED display on the controller. Seven buttons can be used to set treatment time, treatment mode, treatment brightness level, and start or stop treatment. The display screen shows the treatment time, treatment mode and treatment intensity, and is equipped with 4 LED lights to indicate whether the power is connected. When all four lights are on, the current treatment has begun, the controller is directly powered through an adapter.

The controller for the model (E49B, E49C, E100B, E100C, E103B, E104B, E106A, E108A) devices has three buttons to adjust the brightness level, switch modes, set time, and display, The display displays the battery level, treatment mode, time, and brightness information of the current controller, the controller is powered by an internal rechargeable lithium battery.

5. Indications for Use

- Mode 1 (Red + Infrared light): treatment of full face wrinkles.
- Mode 2 (Blue light): Treatment of mild to moderate inflammatory acne.
- Mode 3 (Mixed light): Treatment of mild to moderate inflammatory acne.

6. Comparison to Predicate Devices

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

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Reference Device	Verdict
Company	Shenzhen Eyco Technology Co.,Ltd	Guangdong Newdermo Biotech Co.,Ltd	Marci Beauty Inc	Ambicare Health Ltd	--
Trade Name	LED light therapy mask	LED light therapy mask	Infrared Red Blue LE D Light Heat Beauty Machine	Lustre PRO Light System	--
510(k) Number	K243555	K223544	K210545	K143713	--
Medical Specialty	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same
Regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OLP, OHS	OLP, OHS	OLP, OHS	OLP	Same
Regulation Class	II	II	II	II	Same
Intended use	Mode 1 (Red + Infrared light): treatment of full face wrinkles. Mode 2 (Blue light): Treatment of mild to moderate inflammatory acne. Mode 3 (Mixed light): Treatment of mild to moderate	Red light: Treatment of full-face wrinkles Blue light: Treatment of mild to moderate inflammatory acne. Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle	The Infrared Red Blue LED Light Heat Beauty Machine is an hand-held over-the-counter phototherapy device, the red and infrared light is intended	The Lustre PRO Light system is intended to emit light in the blue region of the light spectrum and is indicated for the treatment of mild to moderate acne vulgaris.	Similar Note1

	inflammatory acne.	spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. Mixed light: Treatment of mild to moderate inflammatory acne.	for the use in treating wrinkles on the face and the blue light is intended for the treatment of the mild to moderate inflammatory acne. This device is indicated for adults only.		
Intended Location of Use	Face	Face and body	Face	Face	Same
Wavelength	Blue: 415nm, Red: 630nm, NIR: 850nm Mixed: 415nm+630nm+850nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Blue:465nm Red:620-630nm IR:845-855nm	Blue: 415nm±15nm	Similar Note 2
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	Same
Intensity (mW/cm2)	R+NIR：6.0~8.0 Blue light:2.0~4.0 Mixed light: 9.0~12.0	Red light: 2.0~3.0 mW/cm2 Blue light:2.0~4.0 mW/cm2 Infrared light: 2.0~4.0 mW/cm2 Mixed light: 9.0~12.0 mW/cm2	Blue Light Mode:5.4 Red Light + NIR Mode:7.2	5	Similar Note 3
Treatment protocol (Treatment time)	Recommended 10minutes each time. 3-4 treatment a week, reduce to 1-2 treatment a week once the results shown.	Manual Mode: 15minutes each time, Automatic Mode: 10minutes each time. 3-4 treatment a week, reduce to 1-2 treatment a week once the results shown.	3 times a week for 30 min. 4weeks	No publicly available	Same
Control	Device uses a timer and software to control treatment duration.	Device uses a timer and software to control treatment duration.	No publicly available	Device uses a timer and software to control treatment duration.	Same

7. <u>Comparison in Detail(s):</u>

<u>Note 1:</u>

Although the “Indications for Use / Intended use” is a little different from the predicate devices, the function of mode 1 for treating full face wrinkles corresponds to the intended use of predicate device 2, with the description that the function of mode 2 for treating mild to moderate acne is consistent with the predicate device 1 and the intended use of reference device, and the mode 3 corresponding to the mixed light mode is consistent with the intended use of the predicate device 1.

Note 2:

Although the “Wavelengths” is a little different from the predicate devices, but wavelengths of the subject device can be covered by the predicate and reference device. Due to the characteristics of LED lights, the emission parameters are showing the peak wavelength of the lamp, and have been assessed by IEC 62471 and IEC 60601-2-57, So, these slight differences will not raise any safety or effectiveness issues.

Note 3:

Although the “Irradiance”, is a little different from the predicate devices, the values of each treatment for these parameters are very close. The irradiance of the subject device is similar to the predicate device 1, predicate device 2 and reference device. The minor differences do not lead to any safety or efficacy issues.

8. Test Summary

8.1 Non-Clinical Tests Performed

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 Edition 3.2 2020-08 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 1-11: 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 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.

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

Biocompatibility

The subject device is biocompatible for its intended use. They are complied with biocompatibility standards ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), ISO 10993-23 (Skin Irritation).

Software verification and validation testing

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.

Usability Testing

Usability testing was conducted on the LED light therapy mask (Models: E43, E32, E49B, E49C, E100B, E100C, E103B, E104B, E106A, E108A), which complies with IEC 62366-1 and IEC 60601-1-6.

Cybersecurity

The subject device no any external interfaces, according to FDA guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”, no need cybersecurity evaluation.

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.

9. Date of the summary prepared: January 7, 2025

10. Final Conclusion

This difference does not raise different risks or concerns of safety and effectiveness compared to the predicate. The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K223544 and K210545.