June 20, 2025

Foshan Guangyu Weilai Medical Equipment Co., Ltd.
℅ Wendy Huang
Technical Manager
Wenzhou ThiWe Business Consulting Co., Ltd.
Room 1203, Building C, Hua'ou Jiayuan
No.50 Tangjiaqiao South Road, Longwan District
Wenzhou, Zhejiang 325000
China

Re: K250880
Trade/Device Name: Led Light Mask (A093)
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: March 3, 2025
Received: March 24, 2025

Dear Wendy Huang:

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: 2025.06.20 10:31:12 -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250880

Device Name
LED LIGHT MASK (A093)

Indications for Use *(Describe)*
- Red light: Treatment of full-face wrinkles.
- Blue light: Treatment of mild to moderate inflammatory acne.
- Red+Blue light: Treatment of mild to moderate inflammatory acne.The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne for adults in home healthcare environment.

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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K250880 - 510(k) Summary

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

1.0 Submitter Information

· Company Name: Foshan Guangyu Weilai Medical Equipment Co., Ltd.

· Address: 201, Block A, Zhongfa Zhaochuang Science and Technology Park, River Village, Lishui Town, Nanhai District, Foshan, Guangdong, 528226, CHINA

· Phone Number: +86-189-25059558

· Contact: Guang Zhou

2.0 Designated Submission Correspondent

· Company Name: Wenzhou ThiWe Business Consulting Co., Ltd.

· Address: Room 1203, Building C, Hua'ou Jiayuan, No.50 Tangjiaqiao South Road, Longwan District, Wenzhou, Zhejiang, 325000, CHINA

· Phone Number: 86-577-88201260

· Contact: Ms. Wendy Huang

· Email: thiwe_reg@outlook.com

3.0 Date of Preparation: June 02, 2025

4.0 Device Information

· Trade/Device Name: LED LIGHT MASK

· Model(s): A093

· Common Name: Over-The-Counter Powered Light Based Laser For Acne;

Light Based Over The Counter Wrinkle Reduction

5.0 Classification

· Device: Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne

· Regulation Description: Laser surgical instrument for use in general and plastic surgery and in dermatology.

· Review Panel: General & Plastic Surgery

· Product Code: OHS; OLP

· Submission Type: 510(k)

· Regulation Number: 878.4810

· Device Class: 2

6.0 Predicate Device Information

· Device Name: LED Light Therapy Mask, Model(s): RB-008G/ RB-008GB/RB-008J/RB-008JB

· 510(k) Number: K243423

· 510(k) Owner: Shenzhen Rainbow Technology Co.,Ltd.

7.0 Device Description

The LED LIGHT MASK adopts light emitting diodes (LED) in the red (635nm ± 5nm) + blue (425 ± 5nm) and red-blue (635nm + 425nm ± 5nm) spectrum to irradiate on the face to realize its therapeutic effect (i.e. treatment of wrinkles and mild to moderate acne. The LED LIGHT MASK adopts the form of a mask that contains 64 LEDs on the inner surface of the main unit. A wired controller is connected to the main unit to control the device, such as turn on/off the device, switch mode (LED color).

The subject device operates in three treatment modes. One mode emits red light, one mode emits blue light, and the third mode emits red-blue light (i.e. mixed light).

To use the device, user should place the mask over the face and use the controller to operate. The device will automatically turn off after each treatment. To prevent irradiation of LED lights to eyes during the treatment, the user must wear the product before turning it on, then the built-in eye mask of the face mask can block the radiation of LED light to the eyes during each treatment.

8.0 Indications for Use

-Red light: Treatment of full-face wrinkles.

-Blue light: Treatment of mild to moderate inflammatory acne.

-Red+Blue light: Treatment of mild to moderate inflammatory acne.

The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne for adults in home healthcare environment.

9.0 Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 1: Comparison Table for Subject and Predicate Device

Item	**Subject Device LED LIGHT MASK, Model: A093**	**Predicate Device LED Light Therapy Mask, Model(s): RB-008G/ RB-008GB/RB-008J/ RB-008JB (K243423)**	**Comparison**
General Comparison			
Regulation number	21 CFR878.4810	21 CFR878.4810; 21 CFR 890.5500	**Similar Analysis 1**

Classification name	Light Based Over The Counter Wrinkle and Acne Reduction	Light Based Over The Counter Wrinkle and Acne Reduction; Infrared lamp.	**Similar Analysis 1**
Product Code	OHS,OLP	OHS,OLP,ILY	**Similar Analysis 1**
Class	II	II	Same
Indications for use	-Red light: Treatment of full-face wrinkles. -Blue light: Treatment of mild to moderate inflammatory acne. -Red+Blue light: Treatment of mild to moderate inflammatory acne. The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne for adults in home healthcare environment.	- Red+Infrared light: Treatment of full-face wrinkles. - Red light: Treatment of full-face wrinkles. - Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. - Blue light: Treatment of mild to moderate inflammatory acne. - Red+Blue light: Treatment of mild to	**Similar Analysis 1**

		moderate inflammatory acne. The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne for adults in home healthcare environment	
Treatment Modes	red light blue light red+blue light	red+infrared light **red light** infrared light **blue light** **red+blue light**	**Similar** **Analysis 1**
Technological Characteristics Comparison			
Location for use	Face	Face	Same
OTC or prescription	OTC	OTC	Same
Power supply	Built-in rechargeable li-ion battery (Model: 802792 3.7V-2500mAh)	lithium batteries	**Similar** **Analysis 2**
Light source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Same
Wavelength	Red(635nm±5nm) Blue(425±5nm) Red-Blue(635nm+425nm ±5nm)	Red(620nm) Blue(460nm) Red+Blue(620nm+460nm) Infrared (850nm)	**Similar** **Analysis 3**
LED power	Red:1.98mW/cm²	Red:53.2mW/cm²	**Different**

	Blue:3.72mW/cm² Red-Blue: 1.24mW/cm²	Blue:58.7mW/cm² Red-Blue: 33.6mW/cm² Red+IR: 45.5mW/cm² IR: 4mW/cm²	**Analysis 4**
Treatment time	It is recommended to use it 3-5 times a week for no more than 30 minutes continuously each time.	Not publicly available	**Different Analysis 5**
Mask design	Yes	Yes	Same
Dimensions(mm)	LED Mask: 225×192×76mm Controller: 53.95×34.00×134.95mm	Not publicly available	**Different Analysis 6**
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471	**Similar Analysis 7**
Biocompatibility feature	All body-contacting materials are complied with relevant ISO10993 standards	All body-contacting materials are complied with relevant ISO10993 standards	Same

Analysis 1: Though the subject device and the predicate device are not identical in classification name, product codes, indications for use, and treatment modes, the classification name, product codes, indications for use, and treatment modes of the subject device are within the range of those of the predicate device, which will not bring new safety and effectiveness concerns.

Analysis 2: The two devices adopt similar power supply, and the power supply of the subject device has been tested according to the requirements of IEC 62133-2, which further ensures the safety of the subject device.

Analysis 3: Though the wavelength(s) of the treatment modes both adopted by the two devices (i.e.red light; blue light; and red-blue light) are not identical, the wavelengths are all within the acceptable range and the wavelengths of the subject device has been verified by FDA recognized standards: IEC 60601-2-57 and IEC 62471, which ensures that the subject device will be as safe and effective for use as the predicate device.

Analysis 4: Though the subject device and predicate device are different in LED power, the LED power of the subject device has been verified by FDA recognized standards: IEC 60601-2-57 and IEC 62471, which ensures that the subject device will be as safe for use as the predicate device.

Analysis 5: Though the two device are not identical in treatment time, the treatment time is based on the intended use, and user can adjust the time and frequency by using the modes described in the instructions for use. So such difference will not bring new safety and effectiveness concerns.

Analysis 6: Though the subject device and predicate device are different in dimensions, such difference is insignificant, which will not raise any safety/effectiveness problems.

Analysis 7: Though the safety standards they adopt is slightly difference. The subject device adopts IEC 60601-2-57, while the predicate device adopts IEC 60601-2-83, both standards are accepted by FDA for verification the safety of light therapy devices, thus will not affecting the substantial equivalence comparison between the two devices.

10.0 Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design

specifications. The test results demonstrated that the proposed device complies with the following standards:

1) Biocompatibility Safety

The materials of the patient-directly contacting components of the A093 LED LIGHT MASK is silicone and performed biocompatibility evaluation in accordance with the following ISO 10993 standards:

· ISO 10993-5 Third edition 2009-06-01

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

· ISO 10993-10 Fourth edition 2021-11

Biological evaluation of medical devices - Part 10: Tests for skin sensitization

· ISO 10993-23 First edition 2021-01

Biological evaluation of medical devices - Part 23: Tests for irritation

2) Electrical Safety and Performance Safety

· ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

· IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION

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 Edition 2.1 2020-07 CONSOLIDATED VERSION

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 62471 First edition 2006-07

Photobiological safety of lamps and lamp systems

· IEC 62133-1 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 1: Nickel systems

3) Software Verification and Validation

Basic Documentation regarding device software in accordance with the FDA Guidance "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023 has been prepared in the submission.

11.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

12.0 Conclusion

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device LED LIGHT MASK, Model: A093 is found to be substantially equivalent to the predicate device: LED Light Therapy Mask, Model(s): RB-008G/ RB-008GB/RB-008J/RB-008JB (K243423).