June 20, 2025

Shenzhen Sunsred Technology Co.,Ltd
% Jun Da Huang
Project Manager
Registrar Corp
Room 502, Bldg A, Phase I, Qianhai Economic and Trade Center
No. 151 Free Trade West Street, Nanshan Sub-district,Qianhai
Shenzhen, Guangdong Province 518066
China

Re: K243978
Trade/Device Name: LED Facial Mask
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, ILY, OLP
Dated: December 10, 2024
Received: December 23, 2024

Dear Jun Da 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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.06.20 15:28:03 -04'00'

for 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)*
K243978

Device Name
LED Facial Mask

Indications for Use *(Describe)*
The LED Facial Mask is an over-the-counter (OTC) device intended for the following uses:
For Red Mode(s): The device emits energy in the red spectrum and is intended for the treatment of full-face wrinkles.
For Red + NIR Mode: The device emits energy in the red and infrared spectrum and is intended for the treatment of full-face wrinkles.
For Blue Mode: The device emits light in the blue region of the spectrum and is specifically indicated for the treatment of mild to moderate acne on the face.
For NIR Mode: The device is intended to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

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

LED Facial Mask

Date of 510(k) Summary Preparation: 2024-12-20
Date of Latest 510(k) Summary Modification: 2025-06-17

1. Applicant Information

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2. Submission Correspondent

Registrar Corp
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Contact Person: HUANG Jun Da Ken
Telephone Number: +86 137 6074 9097
Email: adnil1330@vip.qq.com

3. Proposed Device

Trade Name:	LED Facial Mask
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology. Infrared lamp.
Model(s):	SR-M4
Classification Regulation Number:	21 CFR 878.4810 21 CFR 890.5500
Product Code:	OHS (Light Based Over The Counter Wrinkle Reduction) OLP (Over-The-Counter Powered Light Based Laser For Acne) ILY (Lamp, Infrared, Therapeutic Heating)
Device Class:	II
FDA CDRH Review Panel:	General & Plastic Surgery Physical Medicine

4. Predicate/Reference Device(s)

Predicate Device:

510(k) Number:	K223544
Applicant:	Guangdong Newdermo Biotech Co.,Ltd
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology. Infrared lamp
Trade Name:	LED Light Therapy Mask

This predicate device has not been subject to a design-related recall.

Reference Device #1:

510(k) Number:	K162652
Applicant:	Guangzhou LETA Testing Technology Co., Ltd
Classification Name:	Transcutaneous Electrical Nerve Stimulator For Pain Relief. Laser surgical instrument for use in general and plastic surgery and in dermatology.
Trade Name:	Smart Photon Micro-current Device

This reference device has not been subject to a design-related recall.

Reference Device #2:

510(k) Number:	K163329
Applicant:	Pulsaderm LLC
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Trade Name:	Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72

This reference device has not been subject to a design-related recall.

Reference Device #3:

510(k) Number:	K162489
Applicant:	Zhongshan Bisen Plastic Electronic Products Co.,Ltd.
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Trade Name:	RED Light Device

This reference device has not been subject to a design-related recall.

5. Device Description

The LED Facial Mask is a device used for treatment of full-face wrinkles, mild to moderate acne on the face, and providing topical heating. LEDs housed inside the device emit light onto the face. These LEDs generate blue, red, and infrared wavelengths.

This product is composed of the main device, controller, fastening straps, storage bag, blindfold, and charging cable.

6. Indications for Use

The LED Facial Mask is an over-the-counter (OTC) device intended for the following uses:
For Red Mode(s): The device emits energy in the red spectrum and is intended for the treatment of full-face wrinkles.
For Red + NIR Mode(s): The device emits energy in the red and infrared spectrum and is intended for the treatment of full-face wrinkles.
For Blue Mode: The device emits light in the blue region of the spectrum and is specifically indicated for the treatment of mild to moderate acne on the face.
For NIR Mode: The device is intended to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

7. Comparison to the Predicate Device(s)

Indications for Use/Intended Use:

The subject *LED Facial Mask* is an Over-the-Counter (OTC) device mainly intended for treatment of full-face wrinkles, mild to moderate acne on the face, and providing topical heating. The predicate/reference devices have the same indications for use. All devices share the similar anatomical location and intended use for treatment. The proposed device can be used at home and healthcare settings.

Technological Characteristics:

The subject *LED Facial Mask* has the similar principle of operation and characteristics as the predicate/reference devices. Any minor differences between the subject device and the listed predicate/reference devices do no raise any issues of safety or efficacy. Performance data supports that the device is as safe and effective as the predicate/reference devices for its intended use.

The subject *LED Facial Mask* is substantially equivalent to the predicate/reference devices in that it has the same/similar intended use and technological characteristics, as demonstrated in the following ***Table* 1 *Substantial Equivalence Comparison***.

Table 1 Substantial Equivalence Comparison

Feature	Proposed Device (K243978)	Predicate Device (K223544)	Reference Device #1 (K162652)	Reference Device #2 (K163329)	Reference Device #3 (K162489)	Remarks
Manufacturer	Shenzhen Sunsred Technology CO.,Ltd	Guangdong Newdermo Biotech Co.,Ltd	Guangzhou LETA Testing Technology Co., Ltd	Pulsaderm LLC	Zhongshan Bisen Plastic Electronic Products Co.,Ltd.	/
Device Name	LED Facial Mask	LED Light Therapy Mask	Smart Photon Micro-current Device	Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72	RED Light Device	/
Model(s)	SR-M4	FM-01, FM-02, FM-03	EP-300	Pulsaderm Wrinkle Mask 28 Pulsaderm Wrinkle Mask 72	BZ-0606	/
Intended Use	The LED Facial Mask is an over-the-counter (OTC) device intended for the following uses: For Red Mode(s): The device emits energy in the red spectrum and is intended for the treatment of full-face wrinkles. For Red + NIR Mode(s): The device emits energy in the red and infrared spectrum and is intended for the treatment of full-face wrinkles. For Blue Mode: The device emits light in the blue region of the spectrum and is specifically indicated for the treatment of mild to moderate acne on the face. For NIR Mode: The device is intended to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.	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; for the temporary relief of minor muscle and joint pain, arthritis and muscle 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 micro current stimulation mode: The Smart Photon Micro-current Device is intended for facial stimulation and is indicated for over-the-counter aesthetic use. For red light irradiation mode: The red light is intended for the treatment of periorbital wrinkles, For blue light irradiation mode: The blue light is for the treatment of mild to moderate acne.	The Pulsaderm Wrinkle Masks 28 and 72 are intended for the use in the treatment of facial wrinkles and for people with Fitzpatrick Skin Types I, II and III.	The RED Light Device is an OTC device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.	Same
Rx or OTC	OTC	OTC	OTC	OTC	OTC	Same
Light Source	LED	LED	LED	LED	LED	Same
Product Code	OHS, ILY, OLP	OHS, ILY, OLP	NFO, OHS, OLP	OHS	OHS	Same
Anatomical Location	Face	Face and body	Face	Face	Face	Same
Wavelength	**Blue:** 410 nm 460 nm **Red:** 610 nm 630 nm 660 nm **NIR:** 830 nm 850 nm 880 nm	**Blue:** 460 nm **Red:** 620 nm **Infrared:** 850 nm	**Blue:** 415±10 nm **Red:** 630±10 nm	**Red:** 620～630 nm **Infrared:** 850 nm	**Red:** 633±5 nm **Infrared:** 830±5 nm	Same *Within the range of the predicate devices*
Intensity / Irradiance (mW/cm^2)	**Red1 (Y) Mode:** 36.0 mW/cm^2 **Red2 (R) Mode:** 19.0 mW/cm^2 **Blue (B) Mode:** 6.1 mW/cm^2 **NIR Mode:** 45.0 mW/cm^2 **Red1 (Y)＋NIR Mode:** 81.0 mW/cm^2 **Red2 (R)＋NIR Mode:** 64.0 mW/cm^2	**Red:** 2.0～3.0 mW/cm^2 **Blue:** 2.0～4.0 mW/cm^2 **Infrared:** 2.0～4.0 mW/cm^2 **Mixed:** 9.0～12.0 mW/cm^2	**Red Light Irradiation Mode:** 80 mW/cm^2 **Blued Light Irradiation Mode:** 50 mW/cm^2 **Micro Current Stimulation Mode:** N/A	**Pulsaderm Wrinkle Mask 28:** **Red:** 15.94 mW/cm^2 **Infrared:** 5.24 mW/cm^2 **Total:** 21.18 mW/cm^2 **Pulsaderm Wrinkle Mask 72:** **Red:** 18.71 mW/cm^2 **Infrared:** 6.61 mW/cm^2 **Total:** 25.35 mW/cm^2	**Red:** 70 mW/cm^2 **Infrared:** 55 mW/cm^2 **Total:** 125 mW/cm^2	Same *Total accumulation of treatment energy is within the range of the predicate devices*

Feature	Proposed Device (K243978)	Predicate Device (K223544)	Reference Device #1 (K162652)	Reference Device #2 (K163329)	Reference Device #3 (K162489)	Remarks
Mode	**Red1 (Y) Mode:** 630 nm(55 LEDs) 660 nm(5 LEDs) **Red2 (R) Mode:** 610 nm(5 LEDs) 630 nm(55 LEDs) **Blue (B) Mode:** 410 nm(5 LEDs) 460 nm(55 LEDs) **NIR Mode:** 830 nm(5 LEDs) 850 nm(50 LEDs) 880 nm(5 LEDs) **Red1 (Y)＋NIR Mode:** 630 nm(55 LEDs) 660 nm(5 LEDs) 830 nm(5 LEDs) 850 nm(50 LEDs) 880 nm(5 LEDs) **Red2 (R)＋NIR Mode:** 610 nm(5 LEDs) 630 nm(55 LEDs) 830 nm(5 LEDs) 850 nm(50 LEDs) 880 nm(5 LEDs)	**Red:** 620 nm **Blue:** 460 nm **Infrared:** 850 nm **Mixed:** 460 nm 620 nm 850 nm The number of LEDs is unclear.	**Red Light Irradiation Mode:** 630±10 nm **Blued Light Irradiation Mode:** 415±10 nm The number of LEDs is unclear. **Micro Current Stimulation Mode:** 5 levels of output intensity	Mode configuration is unclear. **Red:** 620～630 nm **Infrared:** 850 nm Pulsaderm Wrinkle Mask 28: Total 28 LEDs Pulsaderm Wrinkle Mask 72: Total 72 LEDs	Mode configuration is unclear. **Red:** 633±5 nm **Infrared:** 830±5 nm 25 LEDs over 17 cm^2	*The difference in number of LEDs does not affect the safety or efficacy of the device as there are a wide range of number of LEDs devices cleared under device code OHS, ILY and OLP.*
Treatment Time	5 minutes per Treatment. DO NOT exceed 5 minutes in one session. 3 days per week for 8 weeks	Manual Mode: 15 minutes each time Automatic Mode: 10 minutes each time. 3-4 treatment a week, reduce to 1-2 treatment a week once the results shown.	For light irradiation of red light, the recommend treatment session is 3 minutes / 2-3 times per week. And for blue light, the recommend treatment session is 4 minutes / 2 times per week on each treatment area.	15 minutes everyday	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time. (5-7 minutes on each treatment zone).	Same *Total accumulation of treatment energy is within the range of the predicate devices*

8. Performance Data

The following performance data are provided in support of the substantial equivalence determination:

The proposed device performs testing in accordance with the following recognized consensus standards:

IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-2:2014+AMD1:2020 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability

IEC 60601-1-11:2015+AMD1:2020 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 60601-2-57:2023 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, cosmetic and aesthetic use

IEC 60601-2-83: 2019+AMD1:2022 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

IEC 62471:2006 Photobiological safety of lamps and lamp systems

IEC 62304:2006+AMD1:2015 Medical Device Software - Software Life Cycle Processes

ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

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 Irritation

9. Clinical/Animal Testing

Clinical/animal testing was not performed for the proposed device as part of the submission.

10. Conclusions

Based on the above performance as documented in this application, the LED Facial Mask is found to have a safety and effectiveness profile that is similar to the predicate devices.