December 24, 2025

Shenzhen Saidi LIght Therapy Technology Co., Ltd.
% Candice Qui
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K253400
Trade/Device Name: LED Light Therapy Mask (FM60X, FM60X-B, FM60X-W, FM80-W, FM80, VAP1, FM100X, FM100X-B, FM100X-W)
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, ILY
Dated: September 28, 2025
Received: September 30, 2025

Dear Candice Qui:

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: 2025.12.24 00:19:52 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253400

Device Name
LED Light Therapy Mask (FM60X, FM60X-B, FM60X-W, FM80-W, FM80, VAP1, FM100X, FM100X-B, FM100X-W)

Indications for Use *(Describe)*
a. Red light: Treatment of full-face wrinkles.
b. 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.
c. Amber light: Treatment of full-face wrinkles.
d. Blue 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K253400

"510(k) Summary" as required by 21 CFR Part 807.92.

Prepared: December 18, 2025

I. Submitter

Shenzhen Saidi Light Therapy Technology Co., Ltd.
4th Floor, Building 3, Yipola Industrial City, Qiaotou Community, Fuhai Street, Baoan District, Shenzhen City, China Zaijun Hu
CEO
Tel: +86 18825271968
Email: smart-grow06@saidipgl.com

II. Device

Name of Device:LED Light Therapy Mask (FM60X, FM60X-B, FM60X-W, FM80-W, FM80, VAP1, FM100X, FM100X-B, FM100X-W)
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: II
Product Code: OHS, OLP, ILY
Regulation Number: 21 CFR 878.4810

III. Predicate Device and Reference Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Guangdong Newdermo Biotech Co., Ltd	LED light therapy mask (FM-01, FM-02, FM-03)	K223544	Feb 23, 2023

Reference device:

Manufacturer	Reference Device	510(k) Number	Approval Date
LED Intellectual Properties, LLC Beijing ADSS Development Co., Ltd.	LightStim for Wrinkles LED Therapy Device	K120775 K192295	March 8, 2012 May 1, 2020

IV. Device Description

The subject device LED LIGHT THERAPY FACE MASK is a home use wearable LED phototherapy device whose purpose is to produce an even and narrow-band of light for the treatment of aesthetic indications including facial wrinkles and acnes.

The subject device consists of a mask body unit that contains light emitting diodes (LEDs), a controller, straps and USB charging cable. And the device is powered by built-in rechargeable lithium battery on the controller.

The LEDs generate 4 kinds of light which include 460nm±5nm blue light, 630±5nm and 660nm±5nm red light, 850±5nm near-infrared light, 605±5nm amber light. A controller is connect to the mask body unit to control the device, such as turn on/off the device, switch LED mode output. And the straps used for securing the mask unit to the body part.

V. Indications for Use

a. Red light: Treatment of full-face wrinkles.
b. 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.
c. Amber light: Treatment of full-face wrinkles.
d. Blue light: Treatment of mild to moderate inflammatory acne.

VI. Comparison of Technological Characteristics With the Predicate Devices

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Remark**
510(k) Number	K253400	K223544	K120775	K192295	/
Trade name	LED LIGHT THERAPY FACE MASK (FM60X, FM60X-B, FM60X-W, FM80-W, FM80, VAP1, FM100X, FM100X-B, FM100X-W)	LED light therapy mask (FM-01, FM-02, FM-03)	LightStim for Wrinkles	LED Therapy Device	/
Manufacturer	Shenzhen Saidi Light Therapy Technology Co., Ltd.	Guangdong Newdermo Biotech Co., Ltd	LED Intellectual Properties, LLC	Beijing ADSS Development Co., Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHS, OLP, ILY	OHS, OLP, ILY	OHS	OLP, OHS	
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	a. Red light: Treatment of full-face wrinkles. b. Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and	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;	The Lighitimn for Wrinkles is an Over-The-Counter handheld device intended for the use in the treatment of full-face wrinkles.	The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne. The device is indicated for adults	Same

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Remark**
	muscle spasm; relieving stiffness, promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. c. Amber light: Treatment of full-face wrinkles. d. Blue light: Treatment of mild to moderate inflammatory acne.	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.		only.	
Location for use	Face	Face and body	Face	Face	Same
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Power supply	Input: AC 100~240V , 50/60 Hz, 0.4A Output: 5V ⎓ 1A	Input: 100-240 V~, 50/60 Hz, 0.25 A Output: DC 5 V, 500 mA	9-volt DC power transformer	5.V DC 2.0 A Powered by direct plug-in adapter: input 100-240V AC50/60 Hz, 0.5AMax., Output 5.0V DC 2.0A	Same
Light source	LEDs	LEDs	LEDs	LEDs	Same
Wavelength	Red: 630±5nm, 660nm±5nm Infrared: 850nm±5nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and	605,630,660,855nm	Red: 630nm±5nm Blue: 4 15nm±5nm	Similar **Note 1**

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Remark**
	Amber: 605±5nm Blue: 460nm±5nm	460nm			
LED Intensity	Red light+Infrared light: Level 1: 30.3mw/cm^2 Level 2: 20.4mw/cm^2 Level 3: 10.3mw/cm^2 Blue light: Level 1: 30mw/cm^2 Level 2: 14.4mw/cm^2 Level 3: 8.4mw/cm^2 Amber light: Level 1: 29.6mw/cm^2 Level 2: 16.7mw/cm^2 Level 3: 8.13mw/cm^2	Red light: 2.0~3.0 mW/cm^2 Blue light: 2.0~4.0 mW/cm^2 Infrared light: 2.0~4.0 mW/cm^2 Mixed light: 9.0~12.0 mW/cm^2	65 mW/cm^2 in contact with LED head	Red light: 80mW/cm2±10% Blue light 50mW/cm2±10%	Similar **Note 2**
Dimensions (mm)	MN1: LED Facial Mask: 300*208.5*5.5mm LED Neck Mask: 338.5*249.7*5.5mm M226: LED Facial Mask: 300*208.5*5.5mm	FM-01: 207X277X43mm, FM-02: 198X383X33.5mm, FM-03: 237.5X108X8.1mm	Unknown	Unknown	**Different** **Note 3**

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Remark**
Treatment Time	10 minutes each time	Manual Mode: 15minutes each time, Automatic Mode: 10minutes each time	3 minutes	Unknown	**Different Note 4**
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	IEC 60601-1 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-57	Same
Biocompatibility feature	All body-contacting materials are complied with ISO 10993-5, ISO 10993-10 and ISO 10993-23	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Unknown	IS0 10993-1, IS0 10993-5, IS0 10993-10	Same

VII.Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Evaluation

The biocompatibility evaluation for the body-contacting components of the Intense pulsed light 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, Document Issued on September 4, 2020", as recognized by FDA. The following testing was performed to, and passed, including:

- 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 skin irritation

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, as per the following standards:

- IEC 60601-1-2: 2014+A1: 2020 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- ANSI AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- 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 60601-2-83: 2019/AMD1: 2022 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62133-2 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

3) Eye Safety

- IEC 62471: 2006 Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with ***basic level*** of documentation 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) Usability

The product usability has been evaluated and verified according to the following FDA guidance

- Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016.

VIII. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device LED LIGHT THERAPY FACE MASK is as safe, as effective, and performs as well as the legally marketed predicate device and reference device.