December 19, 2025

Sunglor Technology Co.,ltd.
Jane Li
Regulatory Supervisor
Room 306, 3nd Floor, building 4, Fuhai science Technology
Industrial Park, Fuyong community, Fuyong street, Baoan Dist
Shenzhen, 518000
China

Re: K253086
Trade/Device Name: LED Light Therapy Device (Models: SG-FM, SG-FE)
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 23, 2025
Received: September 23, 2025

Dear Jane Li:

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: 2025.12.19 22:50:37 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K253086

Device Name
LED Light Therapy Device (Models: SG-FM, SG-FE)

Indications for Use *(Describe)*
The Led Light Therapy Device (Model: SG-FM) is an Over-the-Counter medical device intended for treatment of wrinkles and mild to moderate inflammatory acne.
Red light: Treatment of wrinkles.
Red+Infrared Light: Treatment of wrinkles.
Amber light: Treatment of wrinkles.
Blue Light: Treatment of mild to moderate inflammatory acne.

The Led Light Therapy Device (Model: SG-FE) is an Over-the-Counter medical device intended for treatment of wrinkles.
Red light: Treatment of wrinkles.
Red+Infrared light: Treatment of wrinkles.
Infrared light: Provide topical heating for the purpose of elevating tissue temperature, 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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510k Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K253086
Date of Preparation: 2025-12-18

1. Information of Submitter and correspondent

Submitter's information

Submitter Name: SUNGLOR TECHNOLOGY CO., LTD.
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Submission correspondent's information:

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Address: Room 306, 3rd Floor, building 4, Fuhai science and Technology, Industrial Park, Fuyong community, Fuyong street, Baoan District, Shenzhen, Guangdong, China.
Contact Person: Jane Li
E-mail: 357627482@qq.com

2. Subject Device Identification

Type of 510(k) submission: Traditional
Device Trade Name: LED Light Therapy Device (Models: SG-FM, SG-FE)
Common Name: Light Based Over The Counter Wrinkle Reduction
Over-The-Counter Powered Light Based Laser For Acne
Lamp, Infrared, Therapeutic Heating
Regulation Name:
Laser surgical instrument for use in general and plastic surgery and in dermatology
Infrared lamp
Regulation Medical Specialty: General & Plastic Surgery, Physical Medicine
Review Panel: General & Plastic Surgery, Physical Medicine
Product Code: OHS, OLP, ILY
Regulation Number: 878.4810, 890.5500

Regulation Class: II

3. Predicate Device Information

Sponsor	Dongguan Boyuan Intelligent Technology Co.,Ltd
Device Name	LED Light Therapy Device (KFB290, KFB291)
510(k) Number	K241857
Product Code	OHS, OLP, ILY
Regulation Class	Class II

4. Device Description

The Led Light Therapy Device is an over-the-counter light emitting diode (LED) device that emits energy for use in dermatology for the treatment of wrinkles and mild to moderate inflammatory acne. LED Light Therapy Device is consisting of LED mask, controller, silicone eye protector, USB charging cable and straps.

The LED Light Therapy Device (Model:SG-FM) have 4 types of light, which include Red light (wavelength 630nm), Blue light (wavelength 460nm), Infrared light (wavelength 850nm), and Amber light (wavelength 605nm).

The LED Light Therapy Device (Model:SG-FE) have 2 types of light, which include Red light (wavelength 630nm) and Infrared light (wavelength 850nm).

The LED Light Therapy Device is applied directly to the skin to ensure consistent administration of light during each treatment. The device does not contain any user serviceable components.

The device operates on an internal lithium rechargeable battery. The rechargeable battery can be charged from the external charging adapter through the provided USB Charging Cable.

The USB charging cable is only used for charging, and the device cannot be used while charging.

5. Intended Use/Indications for Use

The Led Light Therapy Device (Model: SG-FM) is an Over-the-Counter medical device intended for treatment of wrinkles and mild to moderate inflammatory acne.

- Red light: Treatment of wrinkles.
- Red+Infrared Light: Treatment of wrinkles.
- Amber light: Treatment of wrinkles.
- Blue Light: Treatment of mild to moderate inflammatory acne.

The Led Light Therapy Device (Model: SG-FE) is an Over-the-Counter medical device intended for treatment of wrinkles.

- Red light: Treatment of wrinkles.
- Red+Infrared light: Treatment of wrinkles.
- Infrared light: Provide topical heating for the purpose of elevating tissue temperature, and to temporarily increase local blood circulation.

6. Substantial Equivalence (SE) Comparison

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

Elements of Comparison	**Subject Device**	**Predicate Device**	**Remark**
Sponsor	SUNGLOR TECHNOLOGY CO.,LTD	Dongguan Boyuan Intelligent Technology Co.,Ltd	N/A
Device Name and Model	Led Light Therapy Device (Models：SG-FM, SG-FE）	LED Light Therapy Device (Model(s): KFB290, KFB291, KFB265, KFB293)	N/A
510 (K) Number	K253086	K241857	N/A
Regulation number	878.4810, 890.5500	878.4810, 890.5500	N/A
Classification Panel	General & Plastic Surgery, Physical Medicine	General & Plastic Surgery Physical Medicine	N/A
Classification	Class II	Class II	N/A
Product code	OHS, OLP, ILY	OHS, OLP, ILY	N/A

Elements of Comparison	Subject Device	Predicate Device	Remark
Indication for Use	The Led Light Therapy Device (Model: SG-FM) is an Over-the-Counter medical device intended for treatment of wrinkles and mild to moderate inflammatory acne. Red light: Treatment of wrinkles. Red+Infrared Light: Treatment of wrinkles. Amber light: Treatment of wrinkles. Blue Light: Treatment of mild to moderate inflammatory acne. The Led Light Therapy Device (Model: SG-FE) is an Over-the-Counter medical device intended for treatment of wrinkles. Red light: Treatment of wrinkles. Red+Infrared light: Treatment of wrinkles. Infrared light: Provide topical heating for the purpose of elevating tissue temperature, and to temporarily increase local blood circulation.	KFB290, KFB291: 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. Red+Infrared Light: Treatment of full-face wrinkles. Amber light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Mixed light (Red+Blue +Infrared): Treatment of mild to moderate inflammatory acne. KFB265, KFB293: Red+Infrared Light: Treatment of wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Amber light: Treatment of wrinkles.	Same

Elements of Comparison	Subject Device	Predicate Device	Remark
Treatment Modes	Model: SG-FM： Red light, Amber light, Blue light, Red+Infrared Light, Model: SG-FE： Red light, Infrared light, Red+Infrared Light.	Red light, Infrared light, Red+Infrared Light, Amber light, Blue light, Mixed light (Red+Blue +Infrared).	Same
Location for use	Face	Face	Same
Intended Environment	Home use	Home use	Same
Type of use	OTC	OTC	Same
Design	Mask	Mask	Same
Dimensions	LED mask: SG-FM:304mm*196mm*4mm SG-FE:304mm*210mm*4mm Controller: 119.5mm*43.5mm*30.2mm;	KFB290: Approximately 302 mm x 197 mm x 22 mm KFB291: Approximately 412 mm x 195 mm x 22 mm	The difference does not raise new questions in safety and effectively.
Power source	Input: DC 5V, 1A Battery: Li-ion rechargeable battery, 3.7V, 3000mAh	Input: 100 -240 V, 50/60 Hz Output: 5V, 1A Lithium ion battery: 1300mAh	The difference does not raise new questions in safety and effectively.
Type of Energy	LEDs	LEDs	Same
Wavelength	**SG-FM:** IR: 850nm±10nm; Red: 630nm±10nm; Amber: 605nm±10nm; Blue: 460nm±10nm; **SG-FE:** IR: 850nm±10nm; Red: 630nm±10nm;	635nm±5nm visible red light; 850nm±5nm Invisible red light; 465±5nm blue light; 605±5nm amber light;	Similar, within range of the predicate's specifications

Elements of Comparison	Subject Device	Predicate Device	Remark
Irradiance	Max Irradiance: 850nm: 3±20%mW/cm^2; 630nm: 22±20%mW/cm^2; 605nm: 14±20%mW/cm^2; 460nm: 13.5±20%mW/cm^2	Red: 25mW/cm^2; IR: 3mW/cm^2; Red+IR: 30mW/cm^2; Blue: 18mW/cm^2 ; Amber: 20mW/cm^2; Mixed light: 9mW/cm^2;	Similar, within range of the predicate's specifications
Treatment time	10/15/20/25/30 minutes	For red, blue and red+infrared: 10, 20, 30 minutes; For infrared, amber light and mixed light: 10, 20 minutes.	Difference, the difference does not raise new questions in safety and effectively.
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Safety	IEC 60601-1 IEC 60601-1-11 IEC 62471 IEC 60601-2-83 IEC 62133-2	IEC 60601-1 IEC 60601-1-11 IEC 62471 IEC 60601-2-83	Same
Biocompatibility compliance	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same

7. Testing Summary

7.1 Non-clinical testing

All necessary performance testing was conducted on the Led Light Therapy Device to support a determination of substantial equivalence to the predicate device.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the LED Light Therapy Device was conducted in accordance with the FDA Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1 Evaluation and testing within a risk management process'" issued on September 8, 2023. 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 irritation

2) **Electrical Safety**

Non-clinical tests were performed on the subject device for 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: 2005 +AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-11:2015+A1:2020 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 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.
- IEC 60601-2-83:2019+A1:2022 Medical electrical equipment Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment.
- IEC 62133-2:2017/AMD1:2021 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 verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff." The software for this device was considered as a Basic Documentation Level, since a failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

7.2 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

8. Final Conclusion

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is as safe, as effective, and performs as well as than the legally marketed predicated device (K241857).