



November 19, 2025

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

Re: K253073

Trade/Device Name: LED Light Therapy Device (SG-FSM, SG-NK, SG-CT)
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
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 Hithe
Digitally signed
by Tanisha Hithe
Date: 2025.11.19
11:23:44 -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

Indications for Use

510(k) Number (if known)

K253073

Device Name

LED Light Therapy Device (SG-FSM, SG-NK, SG-CT)

Indications for Use (Describe)

The Led Light Therapy Device (Model:SG-FSM) is an Over-the-Counter medical device intended for treatment of wrinkles in the face and décolletage area.

Red light: Treatment of wrinkles.

Red+Infrared Light: Treatment of wrinkles.

Amber light: Treatment of wrinkles.

Amber+Infrared Light: Treatment of wrinkles.

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

Red light: Treatment of wrinkles.

Red+Infrared Light: Treatment of wrinkles.

Amber light: Treatment of wrinkles.

Amber+Infrared Light: Treatment of wrinkles.

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

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.

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013_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: K253073

Date of Preparation: 2025-11-19

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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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

Common Name: Light Based Over The Counter Wrinkle Reduction
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, ILY

Regulation Number: 878.4810, 890.5500

Sponsor: SUNGLOR TECHNOLOGY CO.,LTD
Subject Device: LED Light Therapy Device

Regulation Class: II

3. Predicate Device Information

No.	Predicate Device 1	Predicate Device 2	Predicate Device 3
Sponsor	Dongguan Boyuan Intelligent Technology Co.,Ltd	ISMART Developments Ltd	Guangdong Newdermo Biotech Co.,Ltd
Device Name	LED Light Therapy Device (KFB290, KFB291)	décoLITE LED Device (TN2037)	LED light therapy mask (FM-01, FM-02, FM-03)
510(k) Number	K241857	K242382	K223544
Product Code	OHS, OLP, ILY	OHS	OHS, OLP, ILY
Regulation Class	Class II	Class II	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.

LED Light Therapy Device(Model:SG-FSM) is consisting of Flexible silicone panel (LED mask and upper chest), controller, silicone eye protector, USB charging cable and straps.

LED Light Therapy Device(Model:SG-NK, SG-CT) is consisting of Flexible silicone panel (upper chest), controller, USB charging cable and straps.

The LED Light Therapy Device(Model:SG-FSM) have 3 types of light, which include Red light (wavelength 630nm), Infrared light (wavelength 850nm for LED mask, wavelength 830nm for upper chest) and Amber light (wavelength 605nm).

The LED Light Therapy Device(model:SG-NK) have 3 types of light, which include Red light (wavelength 630nm), Infrared light (wavelength 830nm) and Amber light (wavelength 605nm).

The LED Light Therapy Device (Model:SG-CT) have 2 types of light, which include Red light (wavelength 630nm) and Infrared light (wavelength 830nm).

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

(1) The Led Light Therapy Device (Model:SG-FSM) is an Over-the-Counter medical device intended for treatment of wrinkles in the face and décolletage area.

Red light: Treatment of wrinkles.

Red+Infrared Light: Treatment of wrinkles.

Amber light: Treatment of wrinkles.

Amber+Infrared Light: Treatment of wrinkles

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

Red light: Treatment of wrinkles.

Red+Infrared Light: Treatment of wrinkles.

Amber light: Treatment of wrinkles.

Amber+Infrared Light: Treatment of wrinkles.

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

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 1	Predicate Device 2	Predicate Device 3
Sponsor	SUNGLOR TECHNOLOGY CO.,LTD	Dongguan Boyuan Intelligent Technology Co.,Ltd	ISMART Developments Ltd	Guangdong Newdermo Biotech Co.,Ltd

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3
Device Name and Model	Led Light Therapy Device (Model: SG-FSM, SG-NK, SG-CT)	LED Light Therapy Device (KFB290, KFB291)	décoLITE LED Device (TN2037)	LED light therapy mask (FM-01, FM-02, FM-03)
510 (K) Number	K253073	K241857	K242382	K223544
Regulation number	878.4810, 890.5500	878.4810, 890.5500	878.4810	878.4810, 890.5500
Classification Panel	General & Plastic Surgery; Physical Medicine;	General & Plastic Surgery; Physical Medicine;	General & Plastic Surgery;	General & Plastic Surgery; Physical Medicine;
Classification	Class II	Class II	Class II	Class II
Product code	OHS, ILY	OHS, OLP, ILY	OHS	OHS, OLP, ILY
Indication for Use	The Led Light Therapy Device (Model:SG-FSM) is an Over-the-Counter medical device intended for treatment of wrinklesin the face and décolletage area. Red light: Treatment of wrinkles. Red+Infrared Light: Treatment of wrinkles. Amber light: Treatment of wrinkles. Amber+Infrared Light: Treatment of 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. -Red+Infrared Light: Treatment of full-face wrinkles. -Amber light: Treatment of full-face wrinkles. -Blue light: Treatment	The décoLITE LED device is an over-the-counter device that is intended for the use in the treatment of wrinkles in the décolletage area.	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 spasm; Relieving stiffness; promoting the relaxation of Muscle tissue; and to temporarily

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3
	The Led Light Therapy Device (Model:SG-NK) is an Over-the-Counter medical device intended for treatment of wrinkles in the décolletage area. Red light: Treatment of wrinkles. Red+Infrared Light: Treatment of wrinkles. Amber light: Treatment of wrinkles. Amber+Infrared Light: Treatment of wrinkles. The Led Light Therapy Device (Model:SG-CT) is an Over-the-Counter medical device intended for treatment of wrinkles in the décolletage area. Red light: Treatment of wrinkles. Red+Infrared light: Treatment of wrinkles. Infrared light: Provide topical heating for the	of mild to moderate inflammatory acne. -Mixed light(Red+Blue +Infrared): Treatment of mild to moderate inflammatory acne.		increase local blood circulation. Mixed light: Treatment of Mild to moderate inflammatory acne.

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3
	purpose of elevating tissue temperature, and to temporarily increase local blood circulation.			
Location for use	SG-FSM: Face and Decolletage (upper chest) SG-NK and SG-CT: Decolletage (upper chest)	Face	Decolletage (upper chest)	Face and body
Intended Environment	Home use	Home use	Home use	Home use
Type of use	OTC	OTC	OTC	OTC
Dimensions	LED mask for SG-FSM: 304mm*196mm*4 mm Upper chest for SG-FSM and SG-NK: 345mm*224mm*4 mm Upper chest for SG-CT: 337mm*245mm*4 mm 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	Controller: 23mm max (dia) x 104mm (l)	FM-01: 207x 277x 43mm, FM-02: 198x 383x 33.5mm, FM-03: 237.5x 108x 8.1mm
Power source	Input: DC 5V, 1A Battery: Li-ion rechargeable battery,	Input: 100 -240 V, 50/60 Hz Output: 5V, 1A	100-240Vac/47-63Hz. 0.6A Electrical Output: 5V	Input: 100-240V,50/60Hz, 0.25 A; Output: DC

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3
	3.7V, 3000mAh	Lithium ion battery: 1300mAh		5 V, 500mA
Type of Energy	LEDs	LEDs	LEDs	LEDs
Wavelength	SG-FSM: NIR: 850nm (face) and 830nm (upper chest) $\pm$ 10nm; Red: 630nm $\pm$ 10nm; Amber: 605nm $\pm$ 10nm; SG-NK: NIR: 830nm $\pm$ 10nm; Red: 630nm $\pm$ 10nm; Amber: 605nm $\pm$ 10nm; SG-CT: NIR: 830nm $\pm$ 10nm; Red: 630nm $\pm$ 10nm;	635nm $\pm$ 5nm visible red light; 850nm $\pm$ 5nm Invisible red light; 465 $\pm$ 5nm blue light; 605 $\pm$ 5nm amber light;	Red: 630nm $\pm$ 10nm NIR: 830nm $\pm$ 10nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm
Irradiance	Max Irradiance: 850/830nm: 3 $\pm$ 20% μ W/cm ² ; 630nm: 22 $\pm$ 20% μ W/cm ² ; 605nm: 14 $\pm$ 20% μ W/cm ² ;	Red: 25mW/cm ² ; IR: 6mW/cm ² ; Red+IR: 30mW/cm ² ; Blue: 18mW/cm ² ; Amber: 20mW/cm ² ; Mixed light: 9mW/cm ² ;	30mW/cm ² total	Red light:: 2.0~3.0mW/cm ² Blue light: 2.0~4.0mW/cm ² Infrared light:: 2.0~4.0 mW/cm ² Mixed light: 9.0~12.0 mW/cm ²

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3
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.	600 seconds (10 minutes)	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.
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2
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	IEC 60601-1 IEC 60601-1-11 IEC 62471 IEC 60601-2-57 IEC 60601-2-83 IEC 62133-2	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-57
Biocompatibility compliance	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	Unknown	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10

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 “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 8, 2023”, as recommended 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 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 devices(K241857, K242382 and K223544).