September 12, 2025

Dongguan Yanxi Technology Co., Ltd.
% Bing Huang
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518082
China

Re: K252189
Trade/Device Name: LED Light Therapy Mask (2311, 2344, 2457, 2458)
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: July 14, 2025
Received: July 14, 2025

Dear Bing 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: 2025.09.12 10:23:36 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252189

Please provide the device trade name(s).

LED Light Therapy Mask (2311, 2344, 2457, 2458)

Please provide your Indications for Use below.

Red light: Treatment of full-face wrinkles(suitable for model 2344 and model 2457).
Amber light: Treatment of full-face wrinkles.
Blue light: Treatment of mild to moderate inflammatory acne.
Red+Infrared Light: Treatment of full-face wrinkles.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

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

K252189

Date: 2025-09-03

I. Submitter

Dongguan Yanxi Technology Co., LTD.
Room 501, No 19, Guanglong Road, Tianxin Village, Huangjiang Town, Dongguan City, Guangdong Province
Post code: 523763
Tel.: +86 18608323806

Lai xing liang
Title: Quality Supervisor
Tel.: +86 13144884788
Email:342308911@qq.com

II. Device

Name of Device: LED Light Therapy Mask
Model(s): 2311, 2344, 2457, 2458
Common or Usual Name: Light Based Over The Counter Wrinkle Reduction
Over-The-Counter Powered Light Based For Acne
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810

III. Predicate Device & Reference Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
Guangzhou Ahead Intelligent Technology Co., Ltd.	Light Therapy System (Model: M500)	K251042	June 9, 2025
Shenzhen SUNGPO HI-TECH Electronic Co.,Ltd	LED Facial Mask/ MZ-01, NEWKEY-01, SP-FM-01	K230351	May 5, 2023
Shenzhen Siken 3D Technology Development Co., Ltd.	LED Light Therapy Mask/Model: SKB-1818P,SKB-1918,SKB-1918P,SKB-1918PLUS,SKB-	K243040	December 20, 2024

	2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2418		

Reference device:

Manufacturer	Reference Device	510(k) Number	Cleared Date
Dongguan Boyuan Intelligent Technology Co.,Ltd	LED Light Therapy Device (Models: KFB290, KFB291, KFB265, KFB293)	K241857	October 11, 2024
Galactic Beauty, LLC	MMSphereTM	K190443	June 24, 2019

IV. Device Description

The LED Light Therapy Mask adopts light emitting diodes (LED) in the red (630nm±5nm), blue (460nm±5nm), amber (605nm±5nm) and infrared (850nm±10nm) spectrum to irradiate on the face to realize its therapeutic effect. The LED Light Therapy Mask adopts the form of a mask that contains LEDs on the inner surface of the main unit. A controller is connected to the main unit to control the device, such as turn on/off the device, switch mode (LED color), select energy level and adjust time. 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, LED Light Therapy Mask has incorporated protective eye-shield which blocks light energy from LEDs.

V. Indications for Use

Red light: Treatment of full-face wrinkles(suitable for model 2344 and model 2457).
Amber light: Treatment of full-face wrinkles.
Blue light: Treatment of mild to moderate inflammatory acne.
Red+Infrared Light: Treatment of full-face wrinkles.

VI. Comparison of Technological Characteristics With the Predicate Device

LED Light Therapy Mask is compared with the following Predicate Devices and Reference Devices in terms of intended use, design, specifications, and performance:

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**	**Reference Device 1**	**Reference Device 2**	**Remark**
510(k) Number	K252189	K251042	K230351	K243040	K241857	K190443	/
Trade name	LED Light Therapy Mask (Models:2311, 2344, 2457,2458)	Light Therapy System (Model: M500)	LED Facial Mask/ MZ-01, NEWKEY-01, SP-FM-01	LED Light Therapy Mask/Model: SKB-1818P,SKB-1918,SKB-1918P,SKB-1918PLUS,SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2418	LED Light Therapy Device (Models: KFB290, KFB291, KFB265, KFB293)	MMSphere™	/
Manufacturer	Dongguan Yanxi Technology Co.,Ltd	Guangzhou Ahead Intelligent Technology Co., Ltd.	Shenzhen SUNGPO HI-TECH Electronic Co.,Ltd	Shenzhen Siken 3D Technology Development Co., Ltd.	Dongguan Boyuan Intelligent Technology Co.,Ltd	Galactic Beauty, LLC	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810 21 CFR 878.5500	21 CFR 878.4810	Same
Product code	OHS, OLP	OHS, OLP	OHS, OLP	OHS, OLP	OHS, OLP, ILY	OHS, OLP	Same
Device classification	Class II	Class II	Class II	Class II	Class II		Same
Indication for use/ Intended use	2311 and model 2458: Red+Infrared Light: Treatment of full-face	Blue light: Treatment of mild to moderate inflammatory acne.	LED Facial Mask is an over the counter device that is intended to use	LED Light Therapy Mask is an over the counter device that is	KFB290, KFB291: Red light: Treatment of full-face wrinkles.	MMSphereTM Light Therapy Device emits energy in the	Same

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**	**Reference Device 1**	**Reference Device 2**	**Remark**
	wrinkles. Amber light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. 2344 and model 2457: Red light: Treatment of full-face wrinkles. Red+Infrared Light: Treatment of full-face wrinkles. Amber light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne.	Red+IR light: Treatment of facial wrinkles. Amber light: Treatment of facial wrinkles. Mixed light: Treatment of mild to moderate inflammatory acne.	LED light for the treatment of wrinkles and mild to moderate acne.	intended to use LED light for the treatment of wrinkles and mild to moderate 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 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.	red, blue and amber regions of the spectrum, specifically indicated to treat wrinkles and/or mild to moderate acne. The MMSphereTM is designed to be used for 20 minute treatments three to seven times per week.	
Location for use	Face	Face	Face	Face	Face	Face	Same

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**	**Reference Device 1**	**Reference Device 2**	**Remark**
Prescription or OTC	OTC	OTC	OTC	OTC	OTC	OTC	Same
Power supply	Input: DC 5V/1A 2311 and 2344: Lithium polymer Battery 2000mAh 2457: Lithium polymer Battery 4000mAh 2458: Lithium polymer Battery 1000mAh	External adapter 100 -240 V ~ 50 / 60 Hz	An external adapter Input: AC 100-240V 50-60Hz 0.2A Output: DC 12V 0.5A	Input: AC 100-240V 50-60Hz 0.3A Output: DC 5V 1A 3.7V 650mAh Li-ion Battery 3.7V1000mAh Li-ion Battery	Input:100-240V, 50/60Hz Output: 5V, 1A Lithium ion battery: 1300mAh	Unknown	Same
Light source	LEDs	LEDs	LEDs	LEDs	LEDs	LEDs	Same
Wavelength	Red : 630nm±5nm Blue : 460nm±5nm Amber : 605nm±5nm Infrared : 850nm±10nm	Blue: 460nm±5nm Red: 630nm±5nm Amber: 605nm±5nm Near-infrared: 850nm±5nm	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm	SKB-1818P,SKB-1918,SKB-1918P,SKB-1918PLUS: Blue: 460nm±10nm Red: 620nm±10nm SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2418: Blue: 460nm±10nm Red: 620nm±10nm Infrared: 850nm±10nm	KFB290, KFB291: 635nm±5nm visible red light; 850nm±5nm Invisible red light; 465nm±5nm blue light; 605nm±5nm amber light.	605nm 625nm 465nm	Same

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**	**Reference Device 1**	**Reference Device 2**	**Remark**
LED Intensity（mW/cm^2）	2311: Red+IR: 15～22 Blue: 16～29 Amber: 6～10 2344: Red: 21 Blue: 31 Amber: 15 Red+IR: 22 2457: Red: 11～14 Blue:20～27 Amber: 6～9 Red+IR: 9～14 2458: Red+IR: 16 Blue: 20 Amber: 11	M500: Blue: 40mW/cm² Amber: 10mW/cm² Red+IR: 20mW/cm² Mixed mode: 12mW/cm²	Blue: 15~63 Red: 31~75 Amber:15~42	SKB-1818P: Mode 1: Red: 5.5 Mode 2: Blue: 9 SKB-1918: Mode 1: Red: 5 Mode 2: Blue: 6 SKB-1918P： Mode 1: Red: 6 Mode 2: Blue: 6.5 SKB-1918PLUS： Mode 1: Red: 3.5 Mode 2: Blue: 4.0 SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2418: Mode 1: Red：3.5～10 Mode 2: Blue：2.5～8 Mode 3: Red+Infrared Light：6～27	KFB290, KFB291: Red: 25 IR: 3 Red+IR: 30 Blue: 18 Amber: 20 Mixed light: 9	Red 2.45mW/cm^2 Blue 1.33mW/cm^2 Amber: unpublished	Similar **Note 1**
Treatment time	10, 15, 20, 25, 30	10 minutes each time, 3~5 times a week	10 minutes each session.	It is recommended to use it	For red, blue and red+infrared: 10, 20, 30 minutes	20mins/day, 120 days	Same

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**	**Reference Device 1**	**Reference Device 2**	**Remark**
	minutes.		It is recommended to use	for 10 minutes a day, 3 times per week.	For infrared, amber light and mixed light: 10, 20 minutes.		
Electrical safety	IEC 60601-1 IEC 60601-1- 11 IEC 60601-1-2 IEC 60601-2- 83 IEC 62133-2 IEC 62471	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-83 IEC 62471	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC 62471	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-11 EN/IEC 62471 IEC 60601-2-57 IEC 62366-1 EN/IEC 60601-1-6	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471	ANSI/AAMI ES 60601-1 EN 60601-1-2 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-57 IEC 62133-2 IEC 62471	Same
Biocompatibility feature	ISO 10993-5, ISO10993-10, ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	Comply with ISO10993-1, ISO10993-5 and ISO10993-10	ISO 10993-1	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1	Same

VII.Performance Data

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

1) Biocompatibility Safety

The materials of the patient-directly contacting components of the subject device is performed the biocompatibility evaluation 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 –Par t 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 and EMC Safety

Electrical safety and Eye safety testing was performed to, and passed, the following standards:

- 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 compatibility
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11Edition 2.1 2020-07 CONSOLIDATED VERSION, Medical Electrical Equipment –Part 1: 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 60601-2-83:2022, Medical Electrical Equipment - Part 2-83: Particular Requirements For The Basic Safety And Essential Performance Of Home Light Therapy Equipment
- IEC 62133-2 Edition 5.0 2021-09, 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 Documentation*** of concern 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.

Summary

Based on the above performance as documented in this application, the subject device was found to have a safety and effectiveness profile that is similar to the predicate devices and reference devices.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, it can be concluded that the LED Light Therapy Mask is as safe, as effective, and performs as well as the legally marketed predicate devices.