June 6, 2025

Guangzhou Ahead Intelligent Technology Co., Ltd.
% Riley Chan
Registration engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenge International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K251042
Trade/Device Name: Light Therapy System (M500, L6)
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: March 31, 2025
Received: April 3, 2025

Dear Riley Chan:

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: 2025.06.06 13:34:52 -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.	K251042

Please provide the device trade name(s).

Light Therapy System (M500, L6)

Please provide your Indications for Use below.

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.

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)

K251042 - 510(k) Summary

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

I. Submitter

Guangzhou Ahead Intelligent Technology Co., Ltd.
Room 505, Building 2, No.10, Industrial 1st Road, Zhicun, Dashi Street, Panyu District, Guangzhou, Guangdong, China
Post code: 511430

Leo Zheng
General manager
Tel: +86 18664649916
Email: 187308650@qq.com

Prepared date: 2025-6-4

II. Device

Name of Device: Light Therapy System
Model(s): M500, L6
Common or Usual Name: Light Based Over The Counter Wrinkle Reduction
Over-The-Counter Powered Light Based Laser For Acne
Regulation 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	Trade Name	510(k) Number	Cleared Date
Shenzhen SUNGPO HI-TECH Electronic Co.,Ltd	LED Facial Mask/ MZ-01, NEWKEY01, SP-FM-01	K230351	May 5, 2023
Hunan Guangye Biotechnology Co., Ltd.	Beauty LED Mask/ Model: KFB265	K221151	July 19, 2022
Guangdong Newdermo Biotech Co.,Ltd	LED light therapy mask (FM-01, FM-02, FM-03)	K223544	Feb. 23, 2023
Biophotas Inc	Biophotas Celluma3	K171323	Sep. 1, 2017
Ningbo Hesi Electric Co., Ltd	Flexible LED light therapy (Model: HK209)	K200983	July 14, 2021
Shenzhen Aozemei Technology Co., LTD	Micro-current Facial Beauty Device	K241718	Oct. 28, 2024

- Reference device

Manufacturer	Trade Name	510(k) Number	Cleared Date
Marci Beauty Inc	Infrared Red Blue LED Light Heat Beauty Machine	K210545	May 20, 2022
Shenzhen Borria Technology Co., Ltd	LED Therapy Mask (MN1, M226)	K242385	April 7, 2025
Galactic Beauty, LLC	MMSphere	K190443	June 24, 2019

IV. Device Description

The Light Therapy System is an Over-the-Counter (OTC), home-use, wearable light based device, and intended for the use in treating full-face wrinkles and mild to moderate inflammatory acne. Light radiates from the inner surface of the device onto the face. This light is generated by LED with four different spectrum wavelengths: blue (460nm), amber (605nm), red (630nm) and infrared (850nm), and the device has four light treatment, that is, blue light and mixed light mode to treat acne, while amber light mode and red+ IR mode to treat facial wrinkles.

The device is powered by external power supply by connecting with the power adapter and controlled by the controller that should be connected to the main unit. The device's power-on/off, mode switch and treatment time adjustment can be operated by the controller. The device will automatically shut down when the treatment time is over.

V. Indications for Use

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.

VI. Comparison of Technological Characteristics With the Predicate Device

The Light Therapy System has the same intended use as the predicate devices. The technological characteristics such as wavelength, intensity, are similar to the predicate devices. Any minor differences between the subject device and the listed predicate devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate devices for its intended use.
Therefore, the Light Therapy System may be found substantially equivalent to its predicate devices.

Table1: Substantial Equivalence Comparison for M500

Items	Subject device	Primary Predicate device	Predicate device 1	Predicate device 2	Predicate device 3	Reference device 1	Reference device 2	Difference discussion
K number	K251042	K230351	K221151	K223544	K241718	K210545	K190443	/
Device name	Light Therapy System (Model: M500)	LED Facial Mask/ MZ-01, NEWKEY01, SP-FM-01	Beauty LED Mask/ Model: KFB265	LED light therapy mask (FM-01, FM-02, FM-03)	Micro-current Facial Beauty Device, Model: AM-810B, AM-810W, AM-812B, AM- 812W	Infrared Red Blue LED Light Heat Beauty Machine	MMSphere™	/
Product Code	OHS, OLP	OHS, OLP	OHS, OLP	OHS, OLP, ILY	OHS, OLP	OHS, OLP	OHS, OLP	Same
Intended use/ Indications for Use	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 Facial Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	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 increase local blood circulation. Mixed light: Treatment of mild to moderate inflammatory acne.	Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne.	The Infrared Red Blue LED Light Heat Beauty Machine is an hand-held over-the-counter phototherapy device, the red and infrared light is intended for the use in treating wrinkles on the face and the blue light is intended for the treatment of the mild to moderate inflammatory acne. This device is indicated for adults only.	MMSphere™ Light Therapy Device emits energy in the red, blue and amber regions of the spectrum, specifically indicated to treat wrinkles and/or mild to moderate acne. The MMSphere™ is designed to be used for 20 minute treatments three to seven times per week.	Same
Prescription /OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Power supply	External adapter 100 -240 V ~ 50 / 60 Hz	External adapter Input:AC100-240V 50-60Hz 0.2A Output: DC 12V 0.5A	Input: 100 -240 V~, 50/60 Hz Output: 5V 1A	Input: 100-240V~, 50/60Hz, 0,25A Output: DC 5 V, 500 mA	Adapter input: 5V 0.5A Internal battery: 3.7V/600mAh	900mAh, Rechargeable Li-Ion batteries	Unknown	Same

Shape design	M500: Mask	Mask	Mask	Mask	Hand-held Type	Hand-held Type	Handheld and stationary	Similar
Intended location of use	Face	Face	Face	Face and body	Face	Entire Face	Face	Same
Energy type	Light emitting diodes (LEDs)	Light emitting diodes (LEDs)	Light emitting diodes (LEDs)	LED	LED	LED	LED	Same
Wavelength	Blue: 460nm±5nm Red: 630nm±5nm Amber: 605nm±5nm Near-infrared: 850nm±5nm	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm	Red (637nm±5nm)and IR (854nm±5nm); Blue (465±5nm)	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Blue: 415±10nm Amber: 605±10nm Red: 630±10nm	Blue: 465nm Red: 620-630nm IR: 845-855nm	605nm 625nm 465nm	Similar
Intensity (mW/cm^2)	**M500:** Blue: 40mW/cm² Amber: 10mW/cm² Red+IR: 20mW/cm² Mixed mode: 12mW/cm²	Blue: 15~63mW/cm^2 Red: 31~75mW/cm^2 Amber: 15~42mW/cm²	Red+IR: 25.5mW/cm² Blue: 1.36mW/cm²	Red light: 2.0~3.0mW/cm^2 Blue light: 2.0~4.0mW/cm^2 Infrared light: 2.0~4.0mW/cm^2 Mixed light: 9.0~12.0mW/cm^2	Red: 2.5mW/cm^2 Amber: 15mW/cm^2 Blue: 1.4mW/cm^2	Blue light: 5.4mW/cm^2 Red+IR light: 7.2mW/cm^2	Red 2.45mW/cm^2 Blue 1.33mW/cm^2 Amber: unpublished	Similar
Treatment time	10 minutes each time, 3~5 times a week	10 minutes/day, 3 times per week	10min each time	Manual Mode: 15minutes each time. Automatic Mode: 10minutes each time. 3-4 treatment a week, reduce to 1-2 treatment a week once the results shown.	3-5 minutes at a time /2-3 times a week.	3 times a week for 30 min. 4weeks	20mins/day, 120 days	Similar
Main materials	Nylon+spandex, PVC leather, ABS plastic	ABS and PC plastic	Unknown	Unknown	ABS, PC	ABS Plastic and Aluminum Head	Unknown	Different, but solved by biocompatibility test

Table 2: Substantial Equivalence Comparison for L6

Items	Subject device	Primary Predicate device	Predicate device 1	Predicate device 2	Predicate device 3	Predicate device 4	Reference device 1	Reference device 2	Difference discussion
K number	K251042	K171323	K230351	K200983	K223544	K241718	K242385	K190443	/
Device name	Light Therapy System (Model: L6)	Biophotas Celluma3	LED Facial Mask/ MZ-01, NEWKEY01, SP-FM-01	Flexible LED light therapy (Model: HK209)	LED light therapy mask (FM-01, FM-02, FM-03)	Micro-current Facial Beauty Device, Model: AM-810B, AM-810W, AM-812B, AM-812W	LED Therapy Mask (MN1, M226)	MMSphere™	/
Product Code	OHS, OLP	OHS	OHS, OLP	OHS, OLP, ILY	OHS, OLP, ILY	OHS, OLP	OHS, OLP, ILY	OHS, OLP	Same
Intended use/ Indications for Use	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.	The BioPhotas Celluma3 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full face wrinkles.	LED Facial Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	The FLEXIBLE LED LIGHT THERAPY (Model: HK209) is intended to: - The device emitting energy in the blue is intended to reduce the mild to moderate inflammatory acne vulgaris. -The device emitting energy in the red and infrared spectrum is intended for the treatment of full-face wrinkles -The device is intended to deliver heat in the IR spectrum 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	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 increase local blood circulation. Mixed light: Treatment of mild to moderate inflammatory acne.	Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne.	Red light: Treatment of full-face wrinkles. Blue light (only suitable model M226 and MN1 LED Facial Mask): 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 increase local blood circulation.	MMSphere™ Light Therapy Device emits energy in the red, blue and amber regions of the spectrum, specifically indicated to treat wrinkles and/or mild to moderate acne. The MMSphere™ is designed to be used for 20 minute treatments three to seven times per week.	Same

				muscle tissue; and to temporarily increase local blood circulation.			Mixed light: Treatment of full face wrinkles.		
Prescription /OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Power supply	External adapter 100 -240 V ~ 50 / 60 Hz	An AC adaptor for 110-120V	External adapter Input:AC100-240V 50-60Hz 0.2A Output: DC 12V 0.5A	Input: 100–240Vac, 2.0A, 50/60Hz	Input: 100-240V~, 50/60Hz, 0,25A Output: DC 5V, 500mA	Adapter input: 5V 0.5A Internal battery: 3.7V/600mAh	Input: DC 5V, 1A Built-in rechargeable lithium battery: DC 3.7V 2500mAh	Unknown	Same
Shape design	L6: Panel	Panel	Mask	Panel	Mask	Hand-held Type	Mask	Handheld and stationary	Similar
Intended location of use	Face	Whole face	Face	Entire Face and body	Face and body	Face	Face and neck	Face	Same
Energy type	Light emitting diodes (LEDs)	Light emitting diodes (LEDs)	Light emitting diodes (LEDs)	LED	LED	LED	LEDs	LED	Same
Wavelength	Blue: 460nm±5nm Red: 630nm±5nm Amber: 605nm±5nm Near-infrared: 850nm±5nm	Red:640nm+/-25nm NIR:880nm+/-50nm	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm	465nm, 640nm, 880nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Blue: 415±10nm Amber: 605±10nm Red: 630±10nm	Red: 630nm±5nm Blue: 470nm±5nm Near-Infrared: 850nm±5nm Mixed light: 630nm and 850nm	605nm 625nm 465nm	Similar
Intensity (mW/cm^2)	**At 1cm:** Blue: 1.6~3.0mW/cm^2 Amber: 10.5~11.5mW/cm^2 Red+IR: 1.1~2.0mW/cm^2 Mixed: 10~11mW/cm^2 **At 5cm:** Blue: 1.3~2.5mW/cm^2	6.5mW/cm^2	Blue: 15~63mW/cm^2 Red: 31~75mW/cm^2 Amber:15~42mW/cm^2	6.5mW/cm^2	Red light: 2.0~3.0mW/cm^2 Blue light: 2.0~4.0mW/cm^2 Infrared light: 2.0~4.0mW/cm^2 Mixed light: 9.0~12.0mW/cm^2	Red: 2.5mW/cm^2 Amber: 15mW/cm^2 Blue: 1.4mW/cm^2	Red: 0.89~2.55W/cm^2 Blue: 1.44~4.09mW/cm^2 Near-Infrared: 1.83~3.05mW/cm^2 Mixed light: 0.95~2.64mW/cm^2	Red 2.45mW/cm^2 Blue 1.33mW/cm^2 Amber: unpublished	Similar

	Amber: 10.0~11.0mW/cm^2 Red+IR: 0.9~1.5mW/cm^2 Mixed: 9~10mW/cm^2								
The distance between the LEDs to treatment surface	1~5cm	As closed to the skin	As closed to the skin	10cm	As closed to the skin	As closed to the skin	As closed to the skin	Unknown	Similar **Note 4**
Treatment time	10 minutes each time, 3~5 times a week	3 treatments per week (1800 seconds) 4 weeks	10 minutes/day, 3 times per week	3 times a week for 30 min. 4 weeks	Manual Mode: 15minutes each time. Automatic Mode: 10minutes each time. 3-4 treatment a week, reduce to 1-2 treatment a week once the results shown.	3-5 minutes at a time /2-3 times a week.	10 minutes each time	20mins/day, 120 days	Similar
Main materials	Nylon+spandex, PVC leather, ABS plastic	Unknown	ABS and PC plastic	Unknown	Unknown	ABS, PC	Unknown	Unknown	Different, but solved by biocompatibility test

VII.Non-Clinical Testing

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

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the Light Therapy System 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 irritation

2) Electrical Safety and EMC

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

- IEC 60601-1:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2020, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1-11:2020, 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 62471: 2006, Photobiological safety of lamps and lamp systems

3) Software Verification and Validation

Software documentation consistent with ***Basic Documentation level*** 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.

VIII. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device Light Therapy System is as safe, as effective, and performs as well as the legally marketed predicate devices.