October 16, 2025

Merchsource LLC
% Candice Qiu
Registration Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K252093
Trade/Device Name: Light Therapy Mask (1019055)
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, ISA
Dated: June 19, 2025
Received: July 3, 2025

Dear Candice Qiu:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.10.16 09:34:09 -04'00'

for 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252093

Device Name
Light Therapy Mask Model: 1019055

Indications for Use *(Describe)*
The Light Therapy Mask is an over-the-counter device intended for the treatment of full-face wrinkles and mild to moderate inflammatory acne using LED light therapy.
- Red light: Treatment of full-face wrinkles.
- Blue light: Treatment of mild to moderate inflammatory acne.
- Red+Infrared Light: Treatment of full-face wrinkles.
- Mixed light (Red+Blue+Infrared): 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.

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510(k) Summary-K252093

"510(k) Summary" as required by 21 CFR Part 807.92.
September 10, 2025

I. Submitter

MerchSource LLC
7755 Irvine Center Drive Suite 100, Irvine, CA 92618, USA
Shirley Luo
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II. Device

Name of Device: Light Therapy Mask
Model: 1019055
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: II
Product Code: OHS, OLP, ISA
Regulation Number: 21 CFR 878.4810

III. Predicate Device and Reference Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date

Manufacturer	Predicate Device	510(k) Number	Approval Date
Dongguan Boyuan Intelligent Technology Co.,Ltd	LED Light Therapy Device (Model(s): KFB290, KFB291, KFB265, KFB293)	K241857	October 11, 2024

Reference device 1:

Manufacturer	Reference Device	510(k) Number	Approval Date
Shenzhen Siken 3D Technology Development Co., Ltd.	LED Light Therapy Mask/Model: SKB-1818P,SKB-1918,SKB-1918P,SKB-1918PLUS,SKB-2318L,S KB-2318P,SKB-2318PRO,IN-M002,SKB-2418	K243040	December 20, 2024

Reference device 2:

Manufacturer	Reference Device	510(k) Number	Approval Date
Marci Beauty Inc	Infrared Red Blue LED Light Heat Beauty Machine	K210545	May 20, 2022

Reference device 3:

Manufacturer	Reference Device	510(k) Number	Approval Date
Pulsaderm LLC	Pulsaderm Wrinkle Mask 28, Pulsaderm Wrinkle Mask 72	K163329	April 14, 2017

Reference device 4:

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

IV. Device Description

The subject device Light Therapy 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-C charging cable. And the device is powered by built-in rechargeable lithium battery on the controller.

The LEDs generate 3 kinds of light which include Red light (wavelength 635nm±5nm), Blue light (wavelength 465nm±5nm), Infrared light (wavelength 850nm±5nm). A controller is connect to the mask body unit to control the device, such as turn on/off the device. And the straps used for securing the mask unit to the body part.

The device have vibration function, and user can adjust the vibration intensity. Vibration is for general relaxation purposes.

V. Indications for Use

The Light Therapy Mask is an over-the-counter device intended for the treatment of full-face wrinkles and mild to moderate inflammatory acne using LED light therapy.

- Red light: Treatment of full-face wrinkles.
- Blue light: Treatment of mild to moderate inflammatory acne.
- Red+Infrared Light: Treatment of full-face wrinkles.
- Mixed light (Red+Blue+Infrared): Treatment of mild to moderate inflammatory acne.

VI. Comparison of Technological Characteristics With the Predicate Devices

Comparison Elements	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Reference Device 4	Remark
510(k) Number	K252093	K241857	K243040	K210545	K163329	K223544	/
Trade name	Light Therapy Mask (Model:1019055)	LED Light Therapy Device (Models: KFB290, KFB291)	LED light therapy mask	Infrared Red Blue LED Light Heat Beauty Machine	Pulsaderm Wrinkle Mask 28, Pulsaderm Wrinkle Mask 72	LED light therapy mask, Models: FM-01, FM-02, FM-03	/
Manufacturer	MerchSource LLC	Dongguan Boyuan Intelligent Technology Co.,Ltd	Shenzhen Siken 3D Technology Development Co., Ltd.	Marci Beauty Inc	Pulsaderm LLC	Guangdong Newdermo Biotech Co.,Ltd	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	Same
Classification Name	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared Therapeutic Heating(ILY)	Light Based Over The Counter Wrinkle Reduction (OHS)；Over-The-Counter Powered Light Based Laser For Acne(OLP)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Light Based Over the Counter Wrinkle Reduction	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared Therapeutic Heating(ILY)	Same
Product code	OHS, OLP, ISA	OHS, OLP, ILY	OHS, OLP	OHS, OLP	OHS	OHS, OLP, ILY	Same
Device classification	Class II	Class II	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended	The Light Therapy Mask is an over-the-	- Red light: Treatment of full-face wrinkles.	LED Light Therapy Mask is an over the	The Infrared Red Blue LED Light Heat	The Pulsaderm Wrinkle Masks 28	Red light: Treatment of full-face wrinkles. Blue light: Treatment	Same

Comparison Elements	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Reference Device 4	Remark
510(k) Number	K252093	K241857	K243040	K210545	K163329	K223544	/
use	counter device intended for the treatment of full-face wrinkles and mild to moderate inflammatory acne using LED light therapy. - Red light: Treatment of full-face wrinkles. - Blue light: Treatment of mild to moderate inflammatory acne. - Red+Infrared Light: Treatment of full-face wrinkles. - Mixed light (Red+Blue+Infrared): 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. - 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.	counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	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.	and 72 are intended for the use in the treatment of facial wrinkles and for people with Fitzpatrick Skin Types I, II and III.	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.	

Comparison Elements	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Reference Device 4	Remark
510(k) Number	K252093	K241857	K243040	K210545	K163329	K223544	/
Prescription or OTC	OTC	OTC	OTC	OTC	OTC	OTC	Same
Dimension	**LED Mask** 294mm*226.7*18.59mm **Controller** 130.1mm*37mm*25.7 mm	**KFB290:** Approximately 302 mm x 197 mm x 22 mm **KFB291:** Approximately 412 mm x 195 mm x 22 mm	Model SKB-1818P, SKB-1918, SKB-1918P: 194*170*131mm Model SKB-1918PLUS: 217*152*173mm SKB-2318L, SKB-2318P, SKB-2318PRO, IN-FM002, SKB-2418： 411*195*4mm	Not publicly available	Not publicly available	**FM-01:** 207 * 277 * 43 mm, **FM-02:** 198 * 383 * 33.5 mm, **FM-03:** 237.5 * 108 * 8.1 mm	Different **Note 1**
Power supply	Input: DC5V, 1A Battery specifications: Li-ion rechargeable battery 18650 - 2000MAh 3.7V	Input: 100 -240 V, 50 / 60 Hz Output: 5V, 1A Lithium ion battery: 1300mAh	Input: AC 100-240V 50-60Hz 0.3A Output: DC 5V 1A 3.7V 650mAh Li-ion Battery 3.7V1000mAh Li-ion Battery	900mAh, Rechargeable Li-Ion batteries 100~240V AC 50/60HZ 0.5A	Rechargeable Ni-MH battery	Input: 100-240V, 50/60Hz, 0.25 A Output: DC 5 V, 500 mA	Different **Note 2**
Sterilization	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Same
Light source	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Same

Comparison Elements	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Reference Device 4	Remark
510(k) Number	K252093	K241857	K243040	K210545	K163329	K223544	/
Location for use	Face	Face	Face	Entire Face	Face	Face and body	Same
Wavelength	635nm ±5nm visible red light; 850nm±5nm Invisible red light; 465±5nm blue light	635nm ±5nm visible red light; 850nm±5nm Invisible red light; 465±5nm blue light; 605±5nm amber light	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	Blue: 465nm Red: 620-630nm IR: 845-855nm	620-630 nm red and 850 nm Infrared	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Same
Irradiance (mW/cm^2)	Red: 5~20mW/cm^2; Blue: 5~20mW/cm^2; Red+IR: 5~20mW/cm^2; Mixed light: 10mW/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;	SKB-1818P: Mode 1: Red: 5.5mW/cm^2 Mode 2: Blue: 9mW/cm^2 SKB-1918: Mode 1: Red: 5mW/cm^2 Mode 2: Blue: 6mW/cm^2 SKB-1918P：	Blue Light Mode: 5.4 Red+IR Light Mode: 7.2	Red: 15.94 Infrared: 5.24 Total: 21.18	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	Similar **Note 3**

Comparison Elements	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Reference Device 4	Remark
510(k) Number	K252093	K241857	K243040	K210545	K163329	K223544	/
			Mode 1: Red: 6mW/cm^2 Mode 2: Blue: 6.5mW/cm^2 SKB-1918PLUS： Mode 1: Red: 3.5mW/cm^2 Mode 2: Blue: 4.0mW/cm^2 SKB-2318L, SKB-2318P, SKB-2318PRO, IN-FM002, SKB-2418: Mode 1: Red：3.5～10mW/cm^2 Mode 2: Blue：2.5～8mW/cm^2				
Treatment time	5, 10, 15, 20 minutes	For red, blue and red+infrared: 10, 20, 30 minutes For infrared, amber light and mixed light: 10, 20 minutes.	It is recommended to use it for 10 minutes a day, 3 times per week.	8 minutes	15 minutes	**Manual Mode:** 15 minutes each time, **Automatic Mode:** 10 minutes each time.	Similar
Compliance with voluntary	IEC 60601-1;	IEC 60601-1;	IEC 60601-1;	IEC 60601-1;	IEC 60601-1;	IEC 60601-1;	Same

Comparison Elements	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Reference Device 4	Remark
510(k) Number	K252093	K241857	K243040	K210545	K163329	K223544	/
standards	IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471	IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471	IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471 IEC 62133-2	IEC 60601-1-2; IEC 60601-1-11; IEC 62471	IEC 60601-1-2; IEC 62471	IEC 60601-1-2	
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	All body-contacting materials are complied with ISO10993-5, ISO 10993-10 and ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993	All body-contacting materials are complied with ISO10993-5 and ISO 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 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 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
- IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015 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 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62133-2:2017 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 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.

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 Light Therapy Mask is as safe, as effective, and performs as well as the legally marketed predicate device and reference devices.