



April 7, 2025

Shenzhen Borria Technology Co., Ltd
Chardy Wang
Project Leader
501, Floor 5, Building 6, Industrial Zone, No.2015, Shenyang
Road, Pengwan Community, Haishan Street, Yantian District
Shenzhen,
China

Re: K242385

Trade/Device Name: LED Therapy Mask (MN1, M226)

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, OLP

Dated: August 12, 2024

Received: August 12, 2024

Dear Chardy Wang:

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: 2025.04.07
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Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K242385

Device Name

LED Therapy Mask (MN1, M226)

Indications for Use (Describe)

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.

Mixed light: Treatment of full face wrinkles.

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-K242385

"510(k) Summary" as required by 21 CFR Part 807.92.
April 2, 2025

I. Submitter

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II. Device

Name of Device: LED Therapy Mask
Model(s): MN1, M226
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: II
Product Code: OHS, OLP, ILY
Regulation Number: 21 CFR 878.4810

III. Predicate Device and Reference Device

Predicate device:

<u>Manufacturer</u>	<u>Predicate Device</u>	<u>510(k) Number</u>	<u>Approval Date</u>
Guangdong Newdermo Biotech Co., Ltd	LED light therapy mask (FM-01, FM-02, FM-03)	K223544	Feb 23, 2023

Reference device 1:

<u>Manufacturer</u>	<u>Reference Device</u>	<u>510(k) Number</u>	<u>Approval Date</u>
myBlend	MyLedMask	K223147	May 14, 2023

Reference device 2:

<u>Manufacturer</u>	<u>Reference Device</u>	<u>510(k) Number</u>	<u>Approval Date</u>
La Lumiere, LLC	Pro X OTC 5 Light Therapy Device	K140471	Jan 15, 2025

Reference device 3:

<u>Manufacturer</u>	<u>Reference Device</u>	<u>510(k) Number</u>	<u>Approval Date</u>
Trophy Skin Incorporated	Rejuvalite MD	K133896	Nov 13, 2014

IV. Device Description

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

The LEDs generate 4 kinds of light which include Blue light (460nm, only suitable model M226 and MN1 LED Facial Mask), Red light (630nm), Infrared light (850nm) and Mixed light (630nm and 850nm). A controller is connect to the mask body unit to control the device, such as turn on/off the device, switch LED output. And the straps used for securing the mask unit to the body part.

V. Indications for Use

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.

Mixed light: Treatment of full face wrinkles.

VI. Comparison of Technological Characteristics With the Predicate Devices

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Reference Device 3</u>	<u>Remark</u>
510(k) Number	Pending	K223544	K223147	K140471	K133896	/
Trade name	LED Therapy Mask (MN1, M226)	LED light therapy mask (FM-01, FM-02, FM-03)	MyLedMask	Pro X OTC 5 Light Therapy Device	Rejuvalite MD	/

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Reference Device 3</u>	<u>Remark</u>
Manufacturer	SHENZHEN BORRIA TECHNOLOGY CO., LTD	Guangdong Newdermo Biotech Co., Ltd	myBlend	La Lumiere, LLC	Trophy Skin Incorporated	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	<u>Same</u>
Product code	OHS, OLP, ILY	OHS, OLP, ILY	OHS	OHS	OHS	
Device classification	Class II	Class II	Class II	Class II	Class II	<u>Same</u>
Indication for use/ Intended use	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	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	MyLedMask is an over-the-counter device that is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles	The Pro XOTC 5 is an Over-The-Counter device intended for use in the treatment of facial wrinkles. It is for people with wrinkles on their face and who have Fitzpatrick skin types I,II and/or III.	The Rejuvalite MD is an Over the Counter device that is intended for the use in the treatment of full face wrinkles.	<u>Same</u>

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Reference Device 3</u>	<u>Remark</u>
	the relaxation of muscle tissue; and to temporarily increase local blood circulation. Mixed light: Treatment of full face wrinkles.	increase local blood circulation. Mixed light: Treatment of mild to moderate inflammatory acne.				
Location for use	Face and Neck	Face and body	Face and Neck	Full Face	Full Face	<u>Same</u>
Prescription or OTC	OTC	OTC	OTC	OTC	OTC	<u>Same</u>
Power supply	Input: DC 5V, 1A Built-in rechargeable lithium battery: DC 3.7V 2500mAh	Input: 100-240 V~, 50/60 Hz, 0.25 A Output: DC 5 V, 500 mA	Voltage: 100 to 240 volts, AC Frequency:50-60Hz Intensity: 0.35 A	Unknown	AC to DC	<u>Same</u>
Light source	LEDs	LEDs	LEDs	Light-emitting diodes	LEDs	<u>Same</u>
Wavelength	Red: 630nm $\pm$ 5nm Blue: 470 nm $\pm$ 5nm Near-Infrared: 850 nm $\pm$ 5nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Red:630 nm (OSRAM LS T67F) NIR: 850 nm (OSRAM SFH 4253)	Red: 620-640nm IR: 820-880nm	Red 600,622,660nm IR 860nm	<u>Similar</u> Note 1

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Reference Device 3</u>	<u>Remark</u>
	Mixed light: 630nm and 850nm					
LED Intensity	Red: 0.89~2.55mW/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 light: 2.0~3.0 mW/cm ² Blue light: 2.0~4.0 mW/cm ² Infrared light: 2.0~4.0 mW/cm ² Mixed light: 9.0~12.0 mW/cm ²	18.7 mW/cm ² (average of 6 measurement location (including one on the neck) between 10 to 27mW/cm ²)	Red light and IR light: 0.76 mW/cm ²	Red light and IR light: 2.35 mW/cm ²	<u>Similar Note 2</u>
Dimensions (mm)	MN1: LED Facial Mask: 300*208.5*5.5mm LED Neck Mask: 338.5*249.7*5.5mm M226: LED Facial Mask: 300*208.5*5.5mm	FM-01: 207X277X43mm, FM-02: 198X383X33.5mm, FM-03: 237.5X108X8.1mm	LED mask: 176 x342 x 122 Storage case:365 x 225 x150	Unknown	Unknown	<u>Different Note 3</u>
Treatment Time	10 minutes each time	Manual Mode: 15minutes each time, Automatic Mode: 10minutes each time	According to skin phototype, daily - 1 fair skin: 5 min 35 (335 s) - 2 moderately dark skin: 11 min 10 (670 s) - 3 dark	900 seconds	3 minutes daily, 5 days per week for 8 weeks	

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Reference Device 3</u>	<u>Remark</u>
			skin: 13 min 55 (835 s) during 6 to 8 week			
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	Unknown	IEC 60601-1 IEC 60601-1-2	<u>Same</u>
Biocompatibility feature	All body-contacting materials are complied with ISO 10993-5, ISO 10993-10 and ISO 10993-23	All body-contacting materials are complied with ISO 10993-5 and ISO 10993-10	Unknown	Unknown	Unknown	<u>Same</u>

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 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 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 Edition 4.1 2020-09 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-11 Edition 2.1 2020-07 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 Edition 1.0 2017-02, 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 Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with *moderate 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 LED Therapy Mask is as safe, as effective, and performs as well as the legally marketed predicate device and reference devices.