October 17, 2025

Shenzhen Zhenxing Ruitong Technology Co., Ltd.
Li Guoyang
Certification Engineer
Room 25C, Microsoft Science and Technology Building
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K252264
Trade/Device Name: MEGELIN LED Light Therapy Mask (JML1, JML1+JML2); MEGELIN LED Light Therapy Mask (JML3, JML3+JML4); MEGELIN LED Light Therapy Mask (JML5, JML5+JML7); MEGELIN LED Light Therapy Mask (JML6, JML6+JML8); MEGELIN LED Light Therapy Mask (JML9, JML9+JML10)
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 10, 2025
Received: July 21, 2025

Dear Li Guoyang:

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: 2025.10.17 17:56:01 -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

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)*
K252264

Device Name
MEGELIN LED Light Therapy Mask Model(s): JML1, JML1+JML2, JML3, JM3+JML4, JML5, JML5+JM7, JML6, JML6+JML8, JML9, JML9+JML10

Indications for Use *(Describe)*
The MEGELIN LED Light Therapy Mask is an Over-the-Counter (OTC) light based device.
● Red light: Treatment of full-face wrinkles.
● Blue light (only suitable model JML1, JML3, JML5, JML6, JML9 Face mask): 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 of K252264

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

Product Overview

1) SUBMITTER AND OWNER/OPERATOR:

Shenzhen Zhenxing Ruitong Technology Co., Ltd.
Room 25C, Microsoft Science and Technology Building,Nanshan District, Shenzhen City, Guangdong CN 518000
Contact Person : Guoyang Li
Email: liguoyang@jovs-beauty.com
Date prepared: Oct ,15, 2025

2) Product Information

Trade Name: Product name: MEGELIN LED Light Therapy Mask
Model(s): JML1, JML1+JML2, JML3, JM3+JML4, JML5, JML5+JM7, JML6, JML6 +JML8, JML9, JML9+JML10
Common 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
Regulation Number: 21 CFR 878.4810
Product Code: OHS, OLP
Review Panel: General & Plastic Surgery

3) Predicate devices

Primary Predicate device 1

Sponsor	Shenzhen SUNGPO HI-TECH Electronic Co.,Ltd
Device Name and Model	LED Facial Mask, Model(s): MZ-01, NEWKEY-01, SP-FM-01
510(k) Number	K230351
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	Class II

Predicate device2

Sponsor	Shenzhen Borria Technology Co., Ltd
Device Name and Model	LED Therapy Mask (MN1, M226)
510(k) Number	K242385
Product Code	OHS, OLP,ILY
Regulation Number	21 CFR 878.4810
Regulation Class	Class II

Reference device 1

Sponsor	Guangdong Newdermo Biotech Co.,Ltd
Device Name and Model	LED light therapy mask (FM-01, FM-02, FM-03)
510(k) Number	K223544
Product Code	OHS, OLP,ILY
Regulation Number	21 CFR 878.4810 21 CFR 890.5500
Regulation Class	Class II

Reference device 2

Sponsor	Infinitus (China) Company Ltd.
Device Name and Model	BeneLife Premiun Facial Treatment Pack , Model:QZ0701A
510(k) Number	K171647
Product Code	NFO，OHS
Regulation Number	21 CFR 882.5890 21 CFR 878.4810
Regulation Class	Class II

4) Device Description

The MEGELIN LED Light Therapy Mask uses blue light (460nm) to treat acne. The MEGELIN LED Light Therapy Mask uses red light (660nm) to irradiate on the facial skin that help reduce wrinkles.

JML1, JML3, JML5, JML6, JML9 are face masks, with the only difference in energy density setting, while JML2, JML4, JML7, JML8, JML10 are neck masks with the only difference in energy density setting.

5) Proposed Conditions of Use

- Intended Use:

The MEGELIN LED Light Therapy Mask is an Over-the-Counter (OTC) light

based device.

●Red light: Treatment of full-face wrinkles.

●Blue light (only suitable model JML1, JML3, JML5, JML6, JML9 Face mask): Treatment of mild to moderate inflammatory acne.

- Indications: Same as the Intended Use.
- Treatment Area: Face and Neck.

- Target Population:
  The MEGELIN LED Light Therapy Mask is for the crowd aged over 18 years. It can be operated by professional personnel or persons with certain knowledge (the person can study by means of reading the product user manual).

- The Service Life of the Product:
  Product lifetime: 5 years
  Li-battery: More than 1000 hours

- Cleaning Frequency:
  Clean whenever the exterior surface is dirty.

  Dampen a dust-free cloth or non-woven fabric with clean water and clean the areas with dust.

6) Comparison with Predicate Device:

The MEGELIN LED Light Therapy Mask has the same intended use as the predicate devices. The technological characteristics such as wavelength, intensity, are similar to the predicate devices and reference devices. Any minor differences between the subject device and the listed predicate devices and reference devices do not 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 MEGELIN LED Light Therapy Mask may be found substantially equivalent to its predicate devices

Items	Subject device	Primary Predicate device 1	predicate device 2	Reference device 1	Reference device 2	Difference discussion
K number	K252264	K230351	K242385	K223544	K171647	/
Device trade name	MEGELIN LED Light Therapy Mask, Model: JML1, JML1+JML2, JML3, JM3+JML4, JML5, JML5+JM7, JML6, JML6 +JML8, JML9, JML9 +JML10	LED Facial Mask/ MZ-01, NEWKEY01, SP-FM-01	LED Therapy Mask (MN1, M226)	LED light therapy mask (FM-01, FM-02, FM-03)	BeneLife Premiun Facial Treatment Pack ,Model:QZ0 701A Model: EP-300	/
Product Code	OHS, OLP	OHS, OLP	OHS, OLP, ILY	OHS, OLP,ILY	NFO， OHS	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	21 CFR 882.5890， 21 CFR 878.4810	Same
Device Class	Class II	Class II	Class II	Class II	Class II	Same
Intended use	The MEGELIN LED Light Therapy Mask is an Over-the-Counter (OTC) light based device. Red light: Treatment of full-face wrinkles. Blue light (only suitable model JML1,JML3, ,JML5 , JML6,JML9 Face mask): 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.	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	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.	The micro current stimulation mode is intended for facial stimulation and is indicated for over-the counter cosmetic use. The red light treatment function is intended for the treatment of periorbital wrinkles.	Same

			tissue; and to temporarily increase local blood circulation. Mixed light: Treatment of full face wrinkles.	Mixed light: Treatment of mild to moderate inflammatory acne.		
Prescription/ OTC	OTC	OTC	OTC	OTC	OTC	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Same
Intended location of use	Mask and Neck	Mask	Face and Neck	Mask	Mask	Same
Treatment size	JML1, JML3, JML5, JML6, JML9: 330cm^2 JML1+JML2, JML3+JML4, JML5+JML7, JML6+JML8, JML9+JML10: 660cm^2	Unknown	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		Different Note 1
Energy type	LED	LED	LED	LED	LED	Same
Wavelength	Red 660±20nm Blue: 460±20nm	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm	Red: 630nm±5nm Blue: 470 nm±5nm Near-Infrared: 850nm±5nm Mixed light: 630nm and 850nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	660±5nm	Similar Note 2

Intensity (mW/cm^2)	JML1, JML1+JML2: Red: 10mW/cm^2 Blue:15mW/cm^2 JML3, JML3+JML4: Red:15mW/cm^2 Blue: 25mW/cm^2 JML5, JML5+JML7: Red: 20mW/cm^2 Blue: 35mW/cm^2 JML6, JML6+JML8: Red: 25mW/cm^2 Blue: 45mW/cm^2 JML9, JML9+JML10: Red: 35mW/cm^2 Blue: 55mW/cm^2	Blue: 15~63mW/cm^2 Red: 31~75mW/cm^2 Amber: 15~42mW/cm^2	Red: 0.89~2.55mW/cm2 Blue: 1.44~4.09mW/cm2 Near-Infrared: 1.83~3.05mW/cm2 Mixed light: 0.95~2.64mW/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 :80mW/cm2	Similar Note 3
Power supply	Rechargeable Li-ion battery	External adapter Input:AC100-240V 50-60Hz Output: DC 12V 0.5A	Input：DC 5V, 1A Built-in rechargeable lithium battery: DC 3.7V 2500mAh	Unknown	3.7V 2600 mAh rechargeable lithium battery	Different Note 4
Treatment time	10/ 15/ 20 minutes(blue light limited to 10 minutes).	10 minutes/day, 3 times per week	10 minutes each time	Manual Mode: 15minutes each time, Automatic Mode: 10minutes each time.	Red light mode: 3 minutes	Similar
Main materials	Silica gel, ABS, Polyurethane Fiber	ABS and PC plastic	Unknown	Unknown	Unknown	Different, but solved by biocompatibility test

Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	Comply with ISO10993-1, ISO 10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO 10993-5, ISO 10993-10 and ISO 10993-23	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10 requirements.	Same
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 IEC 62133-2	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC62471	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 IEC60601-1-11 IEC60601-2-57	Comply with IEC 60601-1 IEC62471 Comply with IEC 60601-1-2	Same

Comparison in details:

Note 1:

The treatment size is different from the predicate devices and reference devices, but the subject device is a mask design device that is the same as the primary predicate device and predicate device 1, so this difference does not raise any new issues of safety or effectiveness.

Note 2:

Though the wavelength of the subject device is a little different from the primary predicate device, the wavelength of the blue light (460±20nm) of the subject device is basically the same as that of the primary predicate device, while the red light (660±20nm) is the same as the reference device 2, and the subject device complies with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Note 3:

Though the intensity of the subject device is a slightly different from the predicate devices, the intensity range of blue light of the subject device is within the range of that of the primary predicate device, while the intensity range of the red light is within the minimum and maximum range of the predicate devices and reference device 1, and the subject device complies with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Note 4:

The power supply for the subject device is different from that of the predicate devices, however the lithium battery of the subject device has passed IEC 62133-2 test, so this difference should not raise any safety/effectiveness questions.

7) Non-clinical studies and tests performed:

Non-clinical testing have been conducted to verify that the MEGELIN LED Light Therapy Mask meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the subject device complies with 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 1-11: 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 60601-2-83:2022, 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
- IEC 62133-2:2021, 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

The device has been tested for biocompatibility; it complies with the following standards.

- ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro 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

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.

8) Conclusions

MEGELIN LED Light Therapy Mask is substantially equivalent to the predicate device in indications for use and technological characteristics. Any differences that may exist between the subject and predicate devices do not raise questions of safety and effectiveness. MEGELIN LED Light Therapy Mask is as safe, as effective, and performs as well as the predicate devices.