August 4, 2026

Shenzhen Qianyu Technology Co., Ltd.
Li Guoyang
Compliance Manager
Rm. 601, Han'S Technology Center. #9988, Shennanavenue, Maling Community, Yuehai St.,
Nanshandistrict
Shenzhen, Guangdong 518000
China

Re: K261851
Trade/Device Name: LED Light Therapy Mask (JML1, JML1+JML2); LED Light Therapy Mask (JML3, JML3+JML4); LED Light Therapy Mask (JML5, JML5+JML7); LED Light Therapy Mask (JML6, JML6+JML8); 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: June 3, 2026
Received: June 3, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.08.04 22:33:45 -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)*
K261851

Device Name
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)*
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.

510(k) Summary of K261851

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 Qianyu Technology Co., Ltd.
Room 601, Han's Technology Center. No.9988, ShennanAvenue, Maling Community, Yuehai Street, NanshanDistrict, Shenzhen, Guangdong, China
Contact Person: Guoyang Li
Email: liguoyang@jovs-beauty.com
Date prepared: July ,29 , 2026

2) Product Information

Trade Name: Product name: 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

Predicate device

Sponsor	Shenzhen Zhenxing Ruitong Technology Co., Ltd.
Device Name and Model	MEGELIN LED Light Therapy Mask JML1, JML1+JML2, JML3, JM3+JML4, JML5, JML5 +JM7, JML6, JML6+JML8, JML9, JML9 +JML10
510(k) Number	K252264
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	Class II

4) Device Description

The LED Light Therapy Mask uses blue light (460nm) to kill propionibacterium acnes bacteria that causes mild-to-moderate acne. The LED Light Therapy Mask uses red light (660nm) to irradiate on the facial skin that help reduce wrinkles.

5) Proposed Conditions of Use

- Intended Use:

The 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 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 LED Light Therapy Mask has the same intended use as the predicate device. The technological characteristics such as wavelength, intensity, are similar to the predicate device. 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 LED Light Therapy Mask may be found substantially equivalent to its predicate device of K252264

Items	Subject device	Primary Predicate device	Difference discussion
K number	K261851	K252264	/
Device trade name	LED Light Therapy Mask, Model: JML1, JML1 +JML2, JML3, JM3+JML4, JML5, JML5+JM7, JML6, JML6+JML8, JML9, JML9+JML10	MEGELIN LED Light Therapy Mask, Model: JML1, JML1+JML2, JML3, JM3 +JML4, JML5, JML5+JM7, JML6, JML6 +JML8, JML9, JML9+JML10	/
Product Code	OHS, OLP	OHS, OLP	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	Same
Device Class	Class II	Class II	Same
Intended use	The 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.	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.	Same
Prescription/ OTC	OTC	OTC	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Same
Intended	Face and Neck	Face and Neck	Same

location of use			
Treatment size	JML1, JML3, JML5, JML6, JML9: 330cm^2 JML1+JML2, JML3+JML4, JML5+JML7, JML6+JML8, JML9+JML10: 660cm^2	JML1, JML3, JML5, JML6, JML9: 330cm^2 JML1+JML2, JML3+JML4, JML5+JML7, JML6+JML8, JML9+JML10: 660cm^2	Same
Energy type	LED	LED	Same
Wavelength	Red 660±20nm Blue: 460±20nm	Red 660±20nm Blue: 460±20nm	Same
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	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	Same
Power supply	Rechargeable Li-ion battery	Rechargeable Li-ion battery	Same
Treatment time	10/ 15/ 20 minutes(blue light limited to 10 minutes).	10/ 15/ 20 minutes(blue light limited to 10 minutes).	Same

Main materials	Silica gel, ABS, Polyurethane Fiber	Silica gel, ABS, Polyurethane Fiber	Same
Electrical safety	IEC60601-1 IEC60601-1-2 IEC60601-1-11 IEC60601-2-83 IEC62471	IEC60601-1 IEC60601-1-2 IEC60601-1-11 IEC60601-2-83 IEC62471	Same

Non-clinical studies and tests performed:

Non-clinical testing have been conducted to verify that the 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

- **Biocompatibility Rationale**

  The subject device LED Light Therapy Mask, consists of a silica gel mask body, an ABS plastic frame, and a polyurethane fiber lining. In their final finished forms, these components are identical to the corresponding components of the MEGELIN LED Light Therapy Mask (legally marketed U.S. device under 510(k) K252264) in terms of formulation, processing, sterilization, and geometry. No additional chemicals (e.g., plasticizers, fillers, additives, cleaning agents, or mold release agents) are incorporated into any of these components.

  In addition, we have obtained an Authorization to Rely on Biocompatibility Test Report from the reference device manufacturer, which allows us to leverage the biocompatibility data of the predicate device

- **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.

7) Conclusion : 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. LED Light Therapy Mask is as safe, as effective, and performs as well as the predicate device.