December 23, 2025

Dongguan Yijiaming Technology Co., Ltd.
℅ Tulin Lin
Medical Device Consultant
Huide Medical Technology Service Group Co., Ltd
Room 703, Building 16, South Bank Plaza
Exhibition Bay, Zhancheng Community, Fuhai St, Bao'an Dist
Shenzhen, 518103
China

Re: K253135
Trade/Device Name: LED Light Therapy Device (HLGMZ-3W-G1V1,HLGMZ-3W-G2V1,HLG-GJXJ-G1V1,HGMZ-2W-G1V1, HGMZ-2W-G2V1,MRD-GJXJ-G1V1.)
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: OLP, OHS
Dated: September 25, 2025
Received: September 25, 2025

Dear Tulin Lin:

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: 2025.12.23 11:56:17 -05'00'

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)*
K253135

Device Name
LED LIGHT THERAPY DEVICE (HLGMZ-3W-G1V1, HLGMZ-3W-G2V1,HLG-GJXJ-G1V1, HGMZ-2W-G1V1,HGMZ-2W-G2V1,MRD-GJXJ-G1V1)

Indications for Use *(Describe)*
For model:HLGMZ-3W-G1V1,HLGMZ-3W-G2V1,HGMZ-2W-G1V1,HGMZ-2W-G2V1
The LED LIGHT THERAPY MASK is an Over-the-Counter (OTC) light based device
Red light: Treatment of full- face wrinkles (only model HHGMZ-2W-G1V1, HGMZ-2W-G2V1).
Blue light: Treatment of mild to moderate inflammatory acne. (only suitable model HLGMZ-3W-G1V1 and HLGMZ-3W-G2V1)
Mixed light(Red+NIR light): Treatment of full face wrinkles (Model: HLGMZ-3W-G1V1, HLGMZ-3W-G2V1)

For model:HLG-GJXJ-G1V1,MRD-GJXJ-G1V1
The Led Light Therapy for Neck is an Over-the-Counter (OTC) light based device
Red light: Treatment of neck wrinkles (Model: MRD-GJXJ-G1V1)
Mixed light(Red+NIR light): Treatment of neck wrinkles (Model: HLG-GJXJ-G1V1)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

-K253135

1. Submitter of 510(K):

Sponsor:

Company Name:	Dongguan Yijiaming Technology Co., Ltd.
Address:	Room 301, Building 1, No.1, Bikengdong 1st Lane, Dalingshan Town Dongguan City, Guangdong Province, China
Contact person:	Qiang Huang
TEL:	+86-769-88051190
E-mail:	hqzm@yjmled.com

Application Correspondent:

Company Name:	Huide Medical Technology Service Group Co., Ltd
Address:	Room 703, Building 16, South Bank Plaza, Exhibition Bay, Zhancheng Community, Fuhai Street,Shenzhen,Guangdong,518053,China
Contact person:	Mr. Amos Zou
TEL:	+86-15015249549
E-mail:	546977693@qq.com

Date 510(k) Summary Prepared: Sep 25, 2025

2. Proposed Device and code:

Device Name	LED LIGHT THERAPY DEVICE
Model	HLGMZ-3W-G1V1, HLGMZ-3W-G2V1,HLG-GJXJ-G1V1, HGMZ-2W-G1V1,HGMZ-2W-G2V1,MRD-GJXJ-G1V1
Device classification Name:	Over-The-Counter Powered Light Based Laser For Acne; Light Based Over The Counter Wrinkle Reduction.
Regulation Description	Laser surgical instrument for use in general and plastic surgery and in dermatology.; Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	OLP,OHS
Submission Type	510(k)
Regulation Number	878.4810;
Device Class	2

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K230042	Q-Rejuvalight Pro Facewear (Model: P19-0023)	Shenzhen Kaiyan Medical Equipment Co., Ltd
K252264	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)	Shenzhen Zhenxing Ruitong Technology Co., Ltd.

The predicate device has not been subject to a design-related recall.

4. Device Description:

The LED Light Therapy Device is a home-use phototherapy device designed to provide targeted treatment for skin conditions using specific wavelengths of light. The device incorporates advanced LED technology to deliver red (660nm), near-infrared (850nm), and blue (415nm) light. This combination of wavelengths is intended to address two primary skin concerns: full-face wrinkles and mild to moderate inflammatory acne.

Significant Physical and Performance Characteristics:

- Design: The device features a lightweight and ergonomic design, making it comfortable to wear. It includes adjustable head straps and eye pads to ensure a secure and comfortable fit during treatment.
- Materials: The device is constructed from high-quality, durable materials, including nylon fabric and clear silicone, ensuring safety and comfort during use.
- Performance: The device includes 74 LEDs, each with a 3-in-1 chip structure (660nm + 415nm + 850nm), providing dual-mode functionality (Red and Blue Light or Red+IR and Blue light). It offers three adjustable brightness levels (L1-L5) and three timing options (10, 15, 20 minutes) to customize the treatment according to user needs.
- Power Supply: The device is powered by a 5V 2A adapter, with an input voltage range of 100-240V 50/60Hz, ensuring compatibility with various power sources worldwide.

4. Indications for Use

- For model:HLGMZ-3W-G1V1,HLGMZ-3W-G2V1,HGMZ-2W-G1V1,HGMZ-2W-G2V1

The LED LIGHT THERAPY MASK is an Over-the-Counter (OTC) light based device
Red light: Treatment of full- face wrinkles.
Blue light: Treatment of mild to moderate inflammatory acne. (only suitable model HLGMZ-3W-G1V1 and HLGMZ-3W-G2V1)
Mixed light(Red+NIR light): Treatment of full face wrinkles.

- For model:HLG-GJXJ-G1V1,MRD-GJXJ-G1V1

  The Led Light Therapy is an Over-the-Counter (OTC) light based device Red light: Treatment of wrinkles.

  Mixed light(Red+NIR light): Treatment of wrinkles.

5. Comparison of Intended

The following table compares the subject device to the predicate device with respect to the indications for use and technological characteristics:

Predicate Device 1 (Primary)

Elements of comparison	**Predicate Device 1 (**Primary**)**	Subject Device	Verdict
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	Dongguan Yijiaming Technology Co., Ltd.	/
Trade Name	Q-Rejuvalight Pro Facewear	LED LIGHT THERAPY DEVICE	/
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)	SE
510(k) Number	K230042	K253135	SE
Product Code	OHS, OLP	OHS, OLP	SE
Intended Use / Indications for Use	The Q-Rejuvalight Pro Facewear(Model: P19-0023) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.	Red + infrared light mode is used to treat wrinkles all over the face. Red mode is used to treat wrinkles all over the face. Blue mode is used in the treatment of mild to moderate inflammatory acne.	SE
Power source	Input: 5V,50/60Hz, 2A Li-ion Polymer Battery: 3.7V, 600mAh,2.22Wh	100-240VAC Power Adapter	SE
Wavelengths	605nm, 630nm, 660nm, 880nm, 415nm	415±10nm 660±10nm, 850±10nm,	SE
Power Density	Single wavelength: 605nm:15±5mW/cm² 630nm:20±5mW/cm² 660nm:25±5mW/cm²	Red+NIR:40mW/cm²(wrinkle) Red:40mW/cm²(wrinkle) Blue:25mW/cm²(acne)	SE

	880nm:10±5mW/cm² 415nm:25±5mW/cm² Total: 70mW/cm²(wrinkle) 45mW/cm²(acne)		
Irradiance source	LEDs	LEDs	SE
Total Number of LEDs	80pcs	74pcs	Similar Note 2#
LED Distribution	630nm+415nm(Double wick):30pcs 630nm+605nm(Double wick): 25pcs 660nm+880nm(Double wick): 25pcs	222pcs 3-in-1 Chips (660nm+415nm+850nm)	Similar Note 3#
Treatment area	81(acne) 140(wrinkle)	366.21cm²	SE
Treatment time	3 minutes per treatment	Recommended to use for 10-20 minutes for each treatment with 3-5 Treatments per week. Reduce to 3-4 treatments per week once results are visible.	Similar Note 4#
Location for Use	Face	Face	SE
Environment of Use	OTC	OTC	SE
Safety and EMC	IEC 60601-1 IEC 60601-1- 11 IEC 60601-1-2 IEC 60601-2- 57 IEC 62133-2 IEC 62471	IEC 60601-1 IEC 60601-1- 11 IEC 60601-1-2 IEC 60601-2- 83 IEC 60601-2-57 IEC 62471	SE
Biocompatibilit y	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	SE

Predicate Device 2 (Reference)

Elements of comparison	Predicate Device 1 (Reference)	Subject Device	Verdict
K number	K252264	K253135	/

Device trade name	MEGELIN LED Light Therapy Mask, Model: JML1, JML1+JML2, JML3, JM3+JML4, JML5, JML5+JM7, JML6, JML6+JML8, JML9, JML9+JML10	HLG-GJXJ-G1V1, MRD-GJXJ-G1V1	/
Product Code	OHS, OLP	OHS	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Device Class	Class II	Class II	SE
Intended use	The MEGELIN LED Light Therapy Mask is an Overthe-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.	For model:HLG-GJXJ-G1V1, The Led Light Therapy is an Over-the-Counter (OTC) light based device Red light: Treatment of wrinkles. Mixed light(Red+NIR light): Treatment of wrinkles. For model:MRD-GJXJ-G1V1 The Led Light Therapy is an Over-the-Counter (OTC) light based device Red light: Treatment of wrinkles.	Similar Note 1#
Prescription/ OTC	OTC	OTC	SE
Software/Firmware/Microprocessor Control?	Yes	Yes	SE
Intended location of use	Mask and Neck	Neck	Similar Note 1#
Treatment size	JML1, JML3, JML5, JML6, JML9: 330cm^2 JML1+JML2, JML3+JML4, JML5+JML7, JML6+JML8, JML9+JML10: 660cm^2	305.33cm^2	SE
Energy type	LED	LED	SE

Wavelength	Red 660±20nm Blue: 460±20nm	Red:660±10nm Near-Infrared:850±10nm	SE
Intensity (mW/cm2)	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	Red+NIR:40mW/cm²(wrinkle) Red:40mW/cm²(wrinkle)	SE
Power supply	Rechargeable Li-ion battery	100-240VAC Power Adapter	SE
Treatment time	10/ 15/ 20 minutes(blue light limited to 10 minutes).	Recommended to use for 10-20 minutes for each treatment with 3-5 Treatments per week. Reduce to 3-4 treatments per week once results are visible.	SE
Main materials	Silica gel, ABS, Polyurethane Fiber	Silicone Nylon	SE
Biocompatibili ty	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	SE
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 60601-2-83 IEC 62471	SE

Comparison in details:

Note 1#: The product description and technical specs of Predicate Device 2 (reference product, K number K252264, product name: MEGELIN LED Light Therapy Mask) clearly state its intended treatment area as the face and neck. Models JML2, JML4, JML7, JML8, and JML10 are dedicated neck masks, differing from other models only in energy density, with a well-established design basis and application foundation for core neck treatment functions.

The Subject Device (target product, K number K253135, models: HLG-GJXJ-G1V1, MRD-GJXJ-G1V1) is specifically designed for neck wrinkle treatment without facial treatment capabilities. This difference essentially reflects refined targeting of usage scenarios, not altering the core principle of LED light therapy—where specific wavelengths act on skin tissue to reduce wrinkles. In terms of treatment coverage, the Subject Device's range fully aligns with that of Predicate Device 2's dedicated neck masks (JML2, JML4, etc.). Both

products are inherently consistent in neck treatment coverage and target sites, with no blind spots or efficacy deviations from the specialized application area.

Note 2# and 3#:Although the "Total Number of LEDs" and "LED Distribution" of the subject device is slightly different from the predicate devices, the subject device has the same/similar treatment parameters such as the treatment wavelengths and power density designed with the predicate devices. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Although the "Treatment time" of the subject device is different from that of Predicate Device #1 (Primary), it is essentially the same as that of Predicate Device #2 (Referecne). Therefore, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

7. Non-Clinical PERFORMANCE DATA

The testing for LED LIGHT THERAPY DEVICE included electrical safety, electromagnetic compatibility, biocompatibility and bench testing and software. LED LIGHT THERAPY DEVICE passed all testing in support of the substantial equivalence determination:

7.1.Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with
Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"."As dictated by the nature of body contact (intact skin) and contact duration (Prolonged exposure (B), the following endpoints were evaluated for the patient-contacting components:

1) ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2) ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
3) ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

The results of these test demonstrated that the patient-contacting components of the subject device are non-cytotoxic, non-sensitizing, and non-irritating.

7.2. Electrical safety and electromagnetic compatibility

The subject device has been tested in accordance with and found to comply with the following standards:

1) IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2) IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3) IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION 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.
4) IEC TR 60601-4-2:2016, Medical electrical equipment- Part 4-2: Guidance and interpretation -Electromagnetic immunity: performance of medical electrical equipment and medical electrical

systems.
5) IEC 62471: 2006 Photobiological safety of lamps and lamp system.
6) IEC 60601-2-83: 2019+A1:2022 - Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
7) IEC 60601-2-57 Edition 1.0 2011-01 Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.
8) 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

7.3. Software Verification and Validation Testing

In compliance with the requirements specified in the U.S. Food and Drug Administration (FDA) guidance document for industry and FDA staff—***Content of Premarket Submissions for Device Software Functions***—comprehensive Software Verification and Validation (V&V) testing has been completed for this product. Consistent with the ***Basic Documentation Level***, the software documentation has been included in this 510(k) submission, along with full test documentation. System testing results provided in this 510(k) demonstrate that all software requirement specifications have been met, and all software-related hazards have been mitigated to acceptable risk levels.

7.4. Performance Testing

The LED LIGHT THERAPY DEVICE has been subjected to design verification and validation testing. These tests verified and validated the proper operation of the system. The LED LIGHT THERAPY DEVICE device has been found to be adequately safe and effective for the intended users, its intended uses, and use environment. The labeling materials have been found to be easy to use and understandable to the intended users.

8 Summary of Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

9.Conclusions:

The results of the testing described above demonstrate that the LED LIGHT THERAPY DEVICE is as safe and effective as the predicate device and supports a determination of substantial equivalence.