July 15, 2026

Dongguan Miqiang Technology Co., Ltd.
% Charles (Chengyu) Shen
Vice President
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K261407
Trade/Device Name: XPREEN LED Light Therapy Masks (XPRE322, XPRE326, XPRE327, XPRE342, XPRE368, XPRE422, XPRE434, XPRE451, XPRE455, XPRE457, XPRE448, XPRE335, XPRE350, XPRE420, XPRE436, XPRE339, XPRE445)
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: April 29, 2026
Received: April 29, 2026

Dear Charles (Chengyu) Shen:

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: 2026.07.15 15:28:06 -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)*
K261407

Device Name
XPREEN LED Light Therapy Masks

Indications for Use *(Describe)*
XPREEN LED Light Therapy Masks are Over the Counter devices that are intended for the use in the treatment of full face wrinkles and treatment of mild to moderate inflammatory acne.

Red light: Treatment of full-face wrinkles.

Yellow light: Repair and reduce wrinkles.

Infrared light: Provide topical heating for the purpose of elevating tissue temperature; and to temporarily increase local blood circulation.

Blue light: Treatment of mild to moderate inflammatory acne.

Red+Blue light: 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: K261407

1.0 Submitter Information

Dongguan Miqiang Technology Co., Ltd
No. 6, Gongye 1st Road, Hengjiangsha Village, Changping Town, Dongguan City, Guangdong Contact Person: Baotan ZHU
Tel.: +8615362851298
Email: 1069077816@qq.com
Submitter's FDA Registration Number: N/A

Submission Correspondent

Primary Contact:
Charles Shen (Ph. D)
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 1-608-217-9358
Email: cyshen@aol.com

Secondary Contact:
Jinfeng Ning (Ph. D)
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 1-504-256-3616
Email: jfning@gmail.com

Date of Summary: June 30, 2026

2.0 Device Information

Proprietary Name:	XPREEN LED Light Therapy Masks
Common Name:	LED Light Therapy Masks
Classification Name:	Light Based Over the Counter Wrinkle Reduction
Device Classification:	II
Regulation Number:	21 CFR 878.4810
Product Code:	OHS, OLP
Panel:	General & Plastic Surgery

3.0 Predicate Device Information:

	510(K) #	Device Name	Manufacturer
Predicate Device	K253712	Light Therapy Mask (RB-051, RB-061, RB-071, RB-052, RB-062, RB-072, RB-053, RB-063, RB-073)	Shenzhen Rainbow Technology Co., Ltd.
Reference Device 1	K223544	LED light therapy mask (FM-01, FM-02, FM-03)	Guangdong Newdermo Biotech Co., Ltd
Reference Device 2	K241293	LED Light Therapy Device, ELIXIR MD	Yassen Wellness LLC

4.0 Device Description:

The "XPREEN LED Light Therapy Masks" are home use wearable LED phototherapy devices whose purpose are 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 Type-C USB charging cable.

The controller is connected to the mask to control the device operation, such as turning on/off the LED lamps, switching between different LED modes. The strap is used for securing the mask to the face and neck.

The controller is powered by built-in rechargeable lithium battery. The LED generates lights with four different wavelengths and five different therapy modes:

1. Blue Light at 450 nm
2. Yellow Light at 580 nm
3. Red Lights at 630 nm
4. Infrared Light at 830 nm
5. Red and Blue Light at 450/630 nm

Blue light treatment is not available in the neck models.

Each of the "XPREEN LED Light Therapy Masks" provides three treatment options: 10 minutes, 20minutes, and 30minutes.

5.0 Indications for Use:

The "XPREEN LED Light Therapy Masks"are over the counter devices that are intended for use in the treatment of full face wrinkles and treatment of mild to moderate inflammatory acne.

Red light: Treatment of full-face wrinkles.

Yellow light: Repair and reduce wrinkles.

Infrared light: Provide topical heating for the purpose of elevating tissue temperature; and to temporarily increase local blood circulation.

Blue light: Treatment of mild to moderate inflammatory acne.

Red+Blue light: Treatment of mild to moderate inflammatory acne.

6.0 Comparison to Predicate Devices

The "XPREEN LED Light Therapy Masks", marketed by "Dongguan Miqiang Technology Co., Ltd." are compared with the following Predicate Device in terms of intended use, design, material, specifications, and performance.

Predicate Device

(1) K253712, "LED Light Therapy Mask (RB-051, RB-061, RB-071, RB-052, RB-062, RB-072, RB-053, RB-063, RB-073)", manufactured by "Shenzhen Rainbow Technology Co., Ltd."

Reference Device

(1) K223544, "LED light therapy mask (FM-01, FM-02, FM-03)" manufactured by "Guangdong Newdermo Biotech Co., Ltd."
(2) K241293, "LED Light Therapy Device, ELIXIR MD", manufactured by "Yassen Wellness LLC"

The following table shows similarities and differences of use, design, and material between our devices and the predicate device.

Table 5.1: Comparison of Intended Use, Design, and Material

Comparison Items	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
510(k) number		K253712	K223544	K241293
Trade Name	XPREEN LED Light Therapy Masks	LED Light Therapy Mask (RB-051, RB-061, RB-071, RB-052, RB-062, RB-072, RB-053, RB-063, RB-073)	LED Light Therapy Mask	LED Light Therapy Device, ELIXIR MD
Manufacturer	Dongguan Miqiang Technology Co., Ltd.	Shenzhen Rainbow Technology Co., Ltd.	Guangdong Newdermo Biotech Co., Ltd.	Yassen Wellness LLC
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810
Product code	OHS, OLP	OHS, OLP, ILY	OHS, OLP, ILY	GEX
Device classification	Class II	Class II	Class II	Class II
Indication for Use/ Intended Use	XPREEN LED Light Therapy Masks are Over the Counter devices that are intended for the use in the treatment of full face wrinkles and treatment of mild to moderate inflammatory acne. Red light: Treatment of full-face wrinkles. Yellow light: Repair and reduce wrinkles. Infrared light: Provide topical heating for the purpose of elevating tissue temperature; and to temporarily increase local blood circulation. Blue light: Treatment of mild to moderate inflammatory acne. Red+Blue light: Treatment of mild to moderate inflammatory acne.	The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne for adults in home healthcare environment. Red+Infrared light: Treatment of full-face wrinkles. Red light: Treatment of full-face wrinkles. 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. Blue light: Treatment of mild to moderate inflammatory acne. Red+Blue light: Treatment of mild to moderate inflammatory acne.	Red: Treatment of full-face wrinkles. Blue: Treatment of mild to moderate inflammatory acne. Infrared: Topical heating for elevating tissue temperature; arthritis and muscle spasm; etc; and to temporarily increase local blood circulation. Mixed light: Treatment of mild to moderate inflammatory acne.	ELIXIR MDTM use of the red, blue, yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The red light (633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The blue light (417±10 nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The yellow light (590±10nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital

				wrinkles and rhytides. The infrared light (835±15nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.
Prescription or OTC	OTC	OTC	OTC	Prescription
Location for use	Face and body (neck)	Face	Face and body	Face
Power supply	Lithium battery: 3.7V, 1200-5200 mAh (4.44 – 19.24 Wh)	Lithium battery: 5V, 1A	Input: 100-240 V~, 50/60 Hz, 0,25 A Output: DC 5 V, 500 mA	AC 100-240 50/60Hz
Light source	LED	LED	LED	LED
Wavelength	450nm (Blue), 580nm (Yellow), 630nm (Red), 830nm (Infrared)	465nm (Blue), 620nm (Red), 850nm (Infrared)	460 (Blue), 620nm (Red), 850nm (Infrared) Mixed: 620 nm and 850nm and 460nm	417±10 nm (Blue), 633 ±10 nm (Red), 590±10 nm (Yellow), and 835±15 nm (Infrared)
LED Intensity	Red 14.43 mw/cm^2 Blue: 33.90 mw/cm^2, Yellow: 2.55 mw/cm^2 Infrared: 2.70 mw/cm^2 Red+Blue: 24.17 mw/cm^2	Red: 18-26 mw/cm^2 Blue: 31.5-45.5 mw/cm^2, Infrared: 3.6-5.2 mw/cm^2 Red+Blue: 36-52 mw/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	Red light: 20～96 mw/cm² Blue light: 10～120 mw/cm ² Yellow light: 5～35 mw/cm ² Infrared: ≤ 70 mw/cm ² Red/IR: 166mW/cm², Blue/IR: 190mW/cm²

The Indications for Use, working mechanisms, design and technological characteristics of the subject device is similar to the predicate device. The minor differences between the subject device and predicate device do not raise any concerns in terms of safety and effectiveness.

7.0 Non-Clinical Study Summary

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

1) *IEC 60601-1: 2005/AMD1: 2012/AMD2: 2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
2) *IEC 60601-1-2: 2014/ AMD 2020: Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances –Requirements and tests*
3) *IEC TS 60601-4-2:2024: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems*
4) *IEC 60601- 1- 11:2015+A1:2020: 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*
5) *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*
6) *IEC 62471:2006: Photobiological safety of lamps and lamp systems*
7) *IEC 62133-2: 2017/AMD 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*

8.0 Clinical Study Summary

Clinical study is not performed for this product.

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate is that the subject device is as safe, as effective, and performs as well as the legally marketed device (K253712).