October 23, 2026

Shenzhen Xinlong Precision Plastic Mold Products Co., Ltd.
% Qin Wang
RA Specialist
Flying Drug & Medical Compliance Service Co., Ltd.
Rm.1505, Zhenye International Business Center, Qianhai Rd.,
Shenzhen,, GD 518055
China

Re: K262752
Trade/Device Name: Facial Therapy Mask (Z1, Z2,Z3, Z5,Z6, Z7,Z8,Z9)
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: August 3, 2026
Received: August 3, 2026

Dear Qin 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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2026.10.23 12:46:39
-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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262752

Please provide the device trade name(s).

Facial Therapy Mask (Z1, Z2,Z3, Z5,Z6, Z7,Z8,Z9)

Please provide your Indications for Use below.

Models Z1,Z3,Z6,Z8
Red light: Treatment of full-face wrinkles.
Blue light: Treatment of mild to moderate inflammatory acne.
Yellow light+Infrared Light: Treatment of full-face wrinkles.
Red+Blue+Infrared light: Treatment of mild to moderate inflammatory acne;
Models Z2,Z5,Z7,Z9
Red light: Treatment of full-face wrinkles.
Blue light: Treatment of mild to moderate inflammatory acne.
Yellow light+Infrared Light: Treatment of full-face wrinkles.
Red+Blue+Infrared light: Treatment of mild to moderate inflammatory acne;

Please select the types of uses.	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary - K262752

"510(k) Summary" as required by 21 CFR Part 807.92.

I. Submitter

Shenzhen Xinlong Precision Plastic Mold Products CO., LTD.
Address: 3rd Floor, Building A, No. 281 Huating Road, Shuiwei Community, Dalang Street, Longhua District, Shenzhen Guangdong, CN 518110
Contact person: Tianfei He
Title: General Manager
Tel: +86 134 3070 5129
E-mail: 406904985@qq.com
Shenzhen Xinlong Precision Plastic Mold Products CO., LTD.
Date: 2026-07-31

II. Subject Device

Name of Device: Facial Therapy Mask
Model(s): Z1,Z2, Z3,Z5, Z6, Z7,Z8,Z9
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 CRF 878.4810
Product Code: OHS, OLP
Review Panel: General & Plastic Surgery
Device Class: II

III. Predicate Device

No.	510(K) number	Product code	Classification	Trade name
1	K253054	OHS,OLP	Class II	LED Light Therapy Mask
2	K252264	OHS,OLP	Class II	MEGELIN LED Light Therapy Mask
3	K223544	OHS,OLP,ILY	Class II	LED light therapy mask

IV. Device Description

The Facial Therapy Mask is a wearable, non-sterile, reusable and over-the-counter device designed to achieve the aesthetic effect. It consists of main unit, charging cable, controller and user manual. The device is supplied by internal rechargeable lithium battery, which can be recharged by external charger through the Type-C charging cable. The device is un-usable when charging.

Models: Z1, Z3, Z6, Z8

The Facial Therapy Mask adopts light emitting diodes (LED) in the red (660nm ± 10nm), blue(455 ± 10nm), yellow(590 ± 10nm) and infrared (850nm ± 10nm) spectrum to irradiate on the face for the treatment of wrinkles and mild to moderate acne.

Models: Z2, Z5, Z7, Z9

The Facial Therapy Mask integrates phototherapy functionalities. It adopts light emitting diodes (LED) in the red (660nm ± 10nm), blue(455 ± 10nm),yellow(590 ± 10nm) and infrared (850nm ± 10nm) spectrum to irradiate on the face for the treatment of wrinkles and mild to moderate acne.

V. Indications for Use

Models Z1,Z3,Z6,Z8

- Red light: Treatment of full-face wrinkles.
- Blue light: Treatment of mild to moderate inflammatory acne.
- Yellow light+Infrared Light: Treatment of full-face wrinkles.
- Red+Blue+Infrared light: Treatment of mild to moderate inflammatory acne;

Models Z2,Z5,Z7,Z9

- Red light: Treatment of full-face wrinkles.
- Blue light: Treatment of mild to moderate inflammatory acne.
- Yellow light+Infrared Light: Treatment of full-face wrinkles.
- Red+Blue+Infrared light: Treatment of mild to moderate inflammatory acne.

VI. Comparison of Technological Characteristics With the Predicate Device

The Facial Therapy Mask-Phototherapy function Function mode has the same intended use as the predicate device and reference devices. The technological characteristics, features, specifications, materials, and intended use are similar to the predicate device and reference device. Any minor differences between the subject device and the listed predicate device and reference devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device and reference devices for its intended use.
Therefore, The Facial Therapy Mask-Phototherapy function mode may be found substantially equivalent to its predicate devices.

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Remark
510(k) Number	**Pending**	**K253054**	**K252264**	**K223544**	/
Trade name	Facial Therapy Mask Models: Z1, Z2, Z3, Z5, Z6, Z7,Z8,Z9	LED Light Therapy Mask Models M19, M19-1, M19-2, M19-3, M19-5, M19-6	MEGELIN LED Light Therapy Mask, Model: JML1, JML1+JML2, JML3, JM3+JML4, JML5, JML5+JM7, JML6, JML6,+JML8, JML9, JML9+JML10	LED light therapy mask (FM-01, FM-02, FM-03)	/
Manufacturer	SHENZHEN XINLONG PRECISION PLASTIC MOLD PRODUCTS CO., LTD.	SHENZHEN XINLONG PRECISION PLASTIC MOLD PRODUCTS CO., LTD.	Shenzhen Zhenxing Ruitong Technology Co., Ltd.	Guangdong Newdermo Biotech Co.,Ltd	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810,21 CFR 890.5500	Same
Product code	OHS, OLP	OHS, OLP	OHS, OLP	OHS, OLP,ILY	Same
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use	The device is an over the counter device that is intended for Red light: Treatment of full-	The device is an over the counter device that is intended for: Red+Infrared light: Treatment of full-face	The MEGELIN LED Light Therapy Mask is an Over-the-Counter (OTC) light based device. Red light: Treatment	Red light: Treatment,of full-face wrinkles.Blue light: Treatment of mild to moderate inflammatory acne.Infrared	Same

	face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Yellow light+Infrared Light: Treatment of full-face wrinkles. Red+Blue+Infrared light: Treatment of mild to moderate inflammatory acne;	wrinkles; Red+Blue+Infrared light: treatment of mild to moderate inflammatory acne; Yellow+Infrared light: Treatment of full-face wrinkles.	of full-face wrinkles. Blue light (only suitable model JML1,JML3, ,JML5 , JML6,JML9 Face mask): Treatment of mild to moderate inflammatory acne.	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 mild to moderate inflammatory acne.	
Prescription/ OTC	OTC	OTC	OTC	OTC	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes	Same
Intended location of use	Face	Mask and Neck	Face and Neck	Face	Same
Dimension	Z1: 311mm×207mm×3.7mm Z2: 311mm×207mm×6.9mm Z3: 296mm×290mm×3.7mm Z5: 296mm×290mm×6.9mm Z6: 660mm×198mm×3.7mm Z7: 659mm×198mm×6.9mm Z8:233mm×193mm×116.2m	M19: 311mm×200mm×3.5mm M19-1:660mm×190mm×3.5mm M19-2:311mm×191mm×3.5mm M19-3:191mm×211mm×113mm M 19-	JML1, JML3, JML5, JML6, JML9: 330cm2 JML1+JML2, JML3+JML4, JML5+JML7, JML6+JML8, JML9+JML10: 660cm2	FM-01: 207X277X43mm, FM-02: 198X383X33.5mm, FM-03: 237.5X108X8.1mm	Different Note 1

	m Z9:212mm×192mm×113.8mm	5:311mm×191mm×3.5mm M19-6: 311mm×272mm×3.5mm			
Energy type	LED	LED	LED	LED	Same
Wavelength	Mode 1: 660nm (red) Mode 2: 455nm (blue) Mode 3: 590nm+850nm (yellow+infrared light) Mode 4: 660nm+455nm+ 850nm (red+ blue+ infrared light)	Mode 1: 660nm+850nm (red + infrared light) Mode 2: 660nm+460nm+ 850nm (red+blue+infrared light) Mode 3: 590nm+850nm (yellow + infrared light)	Red 660±20nm Blue: 460±20nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Similar Note 2
Intensity (mW/cm^2)	Mode 1 8-25mW/cm^2 Model 2 5-24mW/cm^2 Mode 3 4-12mW/cm^2 Mode 4 10-35mW/cm^2	Mode 1 13-33mW/cm^2 Model 2 11-31mW/cm^2 Mode 3 5-13mW/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/cm2 Blue:45mW/cm^2	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	Similar Note 3

			JML9, JML9+JML10: Red: 35mW/cm^2 Blue: 55mW/cm^2		
Power supply	Lithiumbattery 3.7V, 2000mAh	Lithiumbattery 3.7V, 2000mAh	Rechargeable Li-ion battery	Unknown	Same
Treatment time	5/10/20min	5/10/20min	10/ 15/ 20 minutes(blue light limited to 10 minutes).	Manual Mode: 15minutes each time, Automatic Mode: 10minutes each time.	Same
Main materials	Silica gel, ABS, 304 stainless	Silica gel, ABS,	Silica gel, ABS, Polyurethane Fiber	Unknown	Different, but solved by biocompatibility test
Compliance with voluntary standards	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-83 IEC 62133-2 IEC 62471	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-83 IEC 62133-2 IEC 62471	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-83 IEC 62133-2 IEC 62471	IEC 60601-1; IEC 60601-1-2 IEC60601-1-11 IEC60601-2-57	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Same

VII.Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the Facial Therapy Mask 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 8, 2023", as recommended 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 irritation

2) Electrical Safety

- 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 disturbances - Requirements and tests
- 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
- 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 60601-2-83:2019 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- 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
- Eye Safety

  IEC 62471:2006-07 Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation 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.

VIII. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.