April 4, 2025

Ningbo Dechang Electrical Machinery Made Co.,Ltd
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co.Ltd
Room 1509, Jingting Building, Dongzhou Community
Guangming Street, Guangming District
Shenzhen, Guangdong 518107
China

Re: K242068
Trade/Device Name: LED Light Therapy Mask (RT01)
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 15, 2024
Received: March 10, 2025

Dear Reanny 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.04.04 18:24:35 -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.

Submission Number *(if known)*

K242068

Device Name

LED Light Therapy Mask (RT01)

Indications for Use *(Describe)*

The LED Light Therapy Mask is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. The LED Light Therapy Mask is an over-the-counter device intended to emit energy in the red and Near Infrared spectrum and is intended for the use in the treatment of full-face wrinkles.

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

510(k) number: K242068

1. Information of Submitter and Correspondent

Submitter's information:

Company Name: Ningbo Dechang Electrical Machinery Made Co.,Ltd

Street Address: No.18 YongXing East Road ,Dongjiao Industrial District

City: YuYao

State/ Province: Zhejiang

Country: China

Telephone: +86 15824565056

Fax: /

Contact Person: Yinling Liu

Contact Title: Supply chain manager

Contact Email: christine.liu@dechang-motor.com

Date Prepared: Apr. 03, 2025

Submission correspondent's information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

Address: Room 1509, Jingting Building, Dongzhou Community, Guangming Street, Guangming District, Shenzhen 518107, China

Contact Person: Reanny Wang

E-mail: reanny@reanny.com

Phone: +86(755) 27391220

2. Device Information

Trade Name: LED Light Therapy Mask

Model:	RT01
Common Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name:	Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne
Regulation:	21 CFR § 878.4810
Device Class:	Class 2
Product Code:	OLP, OHS

3. Identification of Predicate Device(s)

Manufacturer	MZ SKIN
Legally Marketed Device	MZ Skin LightMAX Supercharged LED Mask 2.0
510(K) Number	K213184

4. Description of Device

The LED Light Therapy Mask consists of.

1. Face mask
2. Controller
3. Power cable
4. Head strap
5. Base
6. Power adapter

The LED Light Therapy Mask is a home use wearable light emitting diode (LED) phototherapy device whose purpose is to produce an even, cool, narrow band of light for the treatment of full-face wrinkles and mild to moderate acne vulgaris of the face.

The system consists of a Face mask and a controller. The Face mask contains the light emitting diodes (LEDs). The LEDs generate the light. The mask is worn on the face and is held in place by adjustable head strap. The LEDs produce blue, red and near infra-red (NIR) light in the visible spectrum (Blue: 415nm +/- 10nm, Red: 630nm +/- 10nm, NIR 830nm +/-10nm.).

The controller allows the user to select one of two treatment modes (acne or wrinkles) and switches the LEDs ON/OFF, controlling power to the mask. The modes can be selected by

short pressing the Power/mode button. The controller contains a countdown timer and counts down from 10 minutes. The user may stop the treatment during the 10 minutes by long pressing Power/mode button. The controller contains a rechargeable Lithium-ion polymer battery. The controller uses a Power indicator to show the user the battery power level during working status and the charge status during charging. The Power adapter and power cable are used to charge the Lithium battery. The power cable is also used to connect the controller and face mask during working status. The LED Light Therapy Mask cannot be operated while charging.

The LED Light Therapy Mask includes optional heating pads for the lower eyelids, providing localized thermal comfort within a temperature range of 38℃~41℃. The heating function is controlled via the controller and does not interfere with the treatment of acne or wrinkles.

The equipment is not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat. The equipment does not require checks on the light output as the LEDs do not dim with age to any practical extent.

5. Indications for Use

The LED Light Therapy Mask is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. The LED Light Therapy Mask is an over-the-counter device intended to emit energy in the red and Near Infrared spectrum and is intended for the use in the treatment of full-face wrinkles.

6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

6.1 Non-clinical testing

A series of safety and performance tests were conducted on the subject device.

- Product service life
- Software validation
- Electromagnetic compatibility and electrical safety
- Performance test
- Biocompatibility test

All the test results demonstrate LED Light Therapy Mask meets the requirements of its pre-defined acceptance criteria and intended use, and it is substantially equivalent to the predicate device.

6.2 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

7. Performance Summary

Non-Clinical Test

Non clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

IEC60601-1:2005+AMD1: 2012+AMD2: 2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2014+AMD1:2020, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic compatibility-Requirements and tests.

IEC TS 60601-4-2:2024, Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

IEC 60601-1-11:2015+AMD1:2020, 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 60601-2-57:2011,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.

IEC 62471: 2006 Photobiological safety of lamps and lamp systems.

IEC 62133-2: 2017 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 Test:

The subject device is biocompatible for its intended use. They are complied with biocompatibility standards ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), ISO 10993-23 (Irritation), ISO 10993-11 (Acute systemic toxicity) and USP-NF General Chapters 151 (Material mediated Pyrogenicity)

Software verification and validation testing:

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of

appropriate medical care that would likely lead to Minor Injury.

Usability Testing:

Usability testing was conducted on the LED light therapy mask, which complies with IEC 62366-1 and IEC 60601-1-6.

8. Discussion of Comparison to Predicate Devices.

The LED Light Therapy Mask submitted in this 510(k) submission is substantially equivalent in intended use, technological characteristics and performance to the cleared MZ Skin LightMAX Supercharged LED Mask 2.0 **K213184**. Differences between the subject and predicate devices do not raise new questions of safety and effectiveness.

Comparison item	**Subject device**	**Primary predicate device**	**Comparison description**
Device Manufacturer	Ningbo Dechang Electrical Machinery Made Co.,Ltd	MZ SKIN	/
Device Trade Name	LED Light Therapy Mask	MZ Skin LightMAX Supercharged LED Mask 2.0	/
510(K) number	K242068	K213184	/
Classification	Class II Device, OLP, OHS (21 CFR 878.4810)	Class II Device, OLP, OHS (21 CFR 878.4810)	Identical
Use	Over the Counter	Over the Counter	Identical
Intended use and Indications	The LED Light Therapy Mask is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. The LED Light Therapy Mask is an over-the-counter device intended to emit energy in the red and Near Infrared spectrum and is intended for the use in the treatment of full-face wrinkles.	The MZ Skin LightMAX Supercharged LED Mask 2.0 is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. The MZ Skin LightMAX Supercharged LED Mask 2.0 is an over-the-counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face	Identical

Comparison item	Subject device	Primary predicate device	Comparison description
		wrinkles.	
Intended Location of Use	Face	Face	Identical
Energy Type	Light emitting diodes	Light emitting diodes	Identical
Peak Wavelength	Blue: 415nm±10nm, Red: 630nm±10nm, NIR : 830nm±10nm.	Blue: 415nm±10nm, Red: 630nm±10nm, NIR: 830nm±10nm.	Identical
Intensity (mW/cm^2)	Blue: 28mw/cm^2; Red: 16mw/cm^2	Blue 28 mw/cm^2 Red 16 mw/cm^2	Identical
	Red: 18mw/cm^2; NIR: 11mw/cm^2	Red 18 mw/cm^2 NIR 11 mw/cm^2	Identical
Total Intensity (mW/cm^2)	Blue/Red: 44mw/cm^2	Blue/Red 44 mw/cm^2	Identical
	Red/NIR: 29mw/cm^2	Red/NIR 29 mw/cm^2	Identical
Treatment time	10 Minutes	10 Minutes	Identical
Dose	Blue: 16.8J/cm^2; Red: 9.6J/cm^2	Blue 16.8J/cm^2 Red 9.6J/cm^2	Identical
	Red: 11J/cm^2; NIR: 7J/cm^2	Red 11J/cm^2 NIR 7J/cm^2	Identical
Treatment protocol	Acne: 4×weekly, 6 weeks	Acne: 4×weekly, 6 weeks	Identical

Comparison item	Subject device	Primary predicate device	Comparison description
	Wrinkles: 5×weekly, 6 weeks	Wrinkles: 5×weekly, 6 weeks	Identical
Timers/Software Controlled	Device uses a timer and software to control treatment duration.	Device uses a timer and software to control treatment duration.	Identical
Power supply	DC 3.7V / 3800mAh Rechargeable lithium battery	5V, 9.62Wh Lithium Polymer battery	Similar Note 1
Method of attachment	Velcro strap	Velcro strap	Identical
Heating area	Lower eyelids	Not publicly available	Different Note 2
Heating Setting	On and off	Not publicly available	
Heating temperature	38℃~41℃	Not publicly available	

Comparison discussion:

Note 1:

Both the subject device and predicate device are complied with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57 and IEC60601-1-11, the safety and effectiveness of the subject device is verified via tests, so the differences do not affect the safety and effectiveness.

Note 2:

The subject device has optional heating function for lower eyelids, different from the predicate device, but the differences between this function would not adversely impact the safety and effectiveness of the subject device, because the heating function and the treatment function of acne/wrinkles are independent, and the heating area is the lower eyelids, and the treatment area of acne or wrinkles does not include the lower eyelids, so heating function will not affect the treatment effect of acne or wrinkles. Besides, both the predicate device and subject device conform to safety standards of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 and IEC 60601-2-57, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

9. Conclusions

Based on performance testing, comparison and analysis, the subject device LED Light Therapy Mask (model: RT01) is substantially equivalent to the predicate device.