March 23, 2026

Guangdong Newdermo Biotech Co., Ltd.
Jun Yi Xing
Certificate Engineer
Bldg. 70(C28), # 9 Huateng Rd., Jinshan Village,
Shiqi Town, Panyu District
Guangzhou, Guangdong 511450
China

Re: K260202
Trade/Device Name: LED Light Therapy Mask (LumiLips FAC07NA)
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, ILY
Dated: January 23, 2026
Received: January 23, 2026

Dear Jun Yi Xing:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2026.03.23 13:13:47 -04'00'

for 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)*
K260202

Device Name
LED Light Therapy Mask (LumiLips FAC07NA)

Indications for Use *(Describe)*
The LED Light Therapy Mask is an Over-the-Counter (OTC) device intended for treatment of fine lines and wrinkles, and increase in circulation within the perioral region.

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 K260202

Prepared in accordance with the content and format regulatory requirements of 21 CFR Part 807.92

1. Submitter:

510(k) owner's name:	Guangdong Newdermo Biotech Co., Ltd.
Establishment Registration Number:	3013178978
Address:	Building 70(C28), No.9 Huateng Road, Jinshan Village, Shiqi Town, Panyu District, Guangzhou, Guangdong, 511450, P.R. CHINA
Tel:	+86 15012419132
Contact person (including title):	Junyi Xing (Manager)
Email：	sales13@newdermo.com
Preparing date:	March 14, 2026

2. Device name and classification:

Device Name:	LED Light Therapy Mask
Model:	LumiLips FAC07NA
Classification Name	Light Based Over The Counter Wrinkle Reduction Lamp, Infrared, Therapeutic heating
Product code:	OHS, ILY
Regulation Number	21 CFR 878.4810
Regulatory Class:	Class II
Review Panel:	General & Plastic Surgery

3.Premarket Notification Class III Certification and Summary

Not applicable, the subject device is Class II.

4. Predicate Device(s):

1) Predicate device1

Sponsor:	LED Technologies, Inc
Device name:	reVive Perioral
510(k) Number:	K172662

Regulation Number	21 CFR 878.4810
Classification Name	Light Based Over The Counter Wrinkle Reduction Lamp, Infrared, Therapeutic heating
Product Code:	OHS, ILY
Regulatory Class:	Class II
Review Panel:	General & Plastic Surgery

2) Predicate device2

Sponsor:	Shenzhen Kaiyan Medical Co Ltd.
Device name:	Oren LED Perioral Light Therapy System
510(k) Number:	K213024
Regulation Number	21 CFR 878.4810
Classification Name	Light Based Over The Counter Wrinkle Reduction Lamp, Infrared, Therapeutic heating
Product Code:	OHS, ILY
Regulatory Class:	Class II
Review Panel:	General & Plastic Surgery

5. Reason for Submission

New device, there were no prior submissions for the device.

6. Pre-Submission, IDE

Not applicable, there is no prior submission.

7. Device Description:

LED Light Therapy Mask is a home use device. LED Light Therapy Mask - LumiLips FAC07NA uses Light Emitting Diode (LED) energy to treatment of fine lines and wrinkles and increase in circulation within the perioral region. There are 4 kinds of light which include Red light (wavelength 630nm), Dark red light (wavelength 660nm), Near-Infrared light (wavelength 880nm), Amber light (wavelength 605nm).

There is only one model of LED Light Therapy Mask: LumiLips FAC07NA. The product consists of LED lip mask, Mouthpiece, charging cable. The mouthpiece can be removable.

The application area of LumiLips FAC07NA is the lips and surrounding area.

8. Intended Use/Indications for Use:

The LED Light Therapy Mask is an Over-the-Counter (OTC) device intended for treatment of fine lines and wrinkles, and increase in circulation within the perioral region.

9. Predicate Device Comparison

Item	Subject Device	Predicate Device 1 (K172662)	Predicate Device 2 (K213024)	Comparison Result
Trade name	LED Light Therapy Mask	reVive Perioral	Oren LED Perioral Light Therapy System	/
510 (k) number	K260202	K172662	K213024	/
Manufacturer	Guangdong Newdermo Biotech Co.,Ltd.	LED Technologies, Inc	Shenzhen Kaiyan Medical Co Ltd	/
Regulation number	21 CFR 878.4810;	21 CFR 878.4810	21 CFR 878.4810	Same
Regulation Name	Light Based Over The Counter Wrinkle Reduction, Lamp, Infrared, Therapeutic heating	Light Based Over The Counter Wrinkle Reduction, Lamp, Infrared, Therapeutic heating	Light Based Over The Counter Wrinkle Reduction Lamp, Infrared, Therapeutic heating	Same
Product code	OHS, ILY	OHS, ILY	OHS, ILY	Same
Classification	II	II	II	Same
Indications for use/ Intended use	The LED Light Therapy Mask is an Over-the-Counter (OTC) device intended for treatment of fine lines and wrinkles, and increase in circulation within the perioral region.	The reVive® Perioral LED Light Therapy system is an Over-the-Counter (OTC) device intended for treatment of fine lines and wrinkles, and increase in circulation within the perioral region.	The Oren LED Perioral Light Therapy System (Model: OR-01) is an Over-the-Counter (OTC) device intended for the treatment fine lines and wrinkles, and increase in circulation within the perioral region.	Same
Location for use	Lips and surrounding area	Face include Lip	Perioral region	Similar Note1
OTC or prescription	OTC	OTC	OTC	Same

Power supply	Input: 5V⎓ 0.35A; Li-ion Polymer Battery: DC 3.7V, 500mAh, 1.85Wh	LI-Ion Battery 5V USB & 3.7 V Battery	3.7V lithium battery	Similar Note2
Power Source	Battery or Universal USB power source	Battery or Universal USB power source	Battery or Universal USB power source	Same
Light source	LEDs	LEDs	LEDs	Same
Wavelengths	605nm, 630nm, 660nm, 880nm,	605nm, 630nm, 660nm, 880nm	605nm, 630nm, 660nm, 880nm	Same
Power Density	Red light (630nm) + Amber light (605nm) + Dark Red light (660nm) + Near-Infrared light (880nm): 40mW/cm² ± 20%.	Red light (630 nm) + Amber light (605 nm) + Dark Red light (660 nm) + Near - Infrared light (880 nm): 67.7 mW/cm²	Red light (630 nm) + Amber light (605 nm) + Dark Red light (660 nm) + Near - Infrared light (880 nm): 67.7 mW/cm² ± 10% mW/cm²	Similar Note3
Dose(J/cm²)	60×5×40÷1000=12 J/cm²	60×3×67.7÷1000≈12 J/cm²	60×3×67.7÷1000≈12 J/cm²	Same
Treatment time	The session begins and lasts for 5 minutes for modes M1.	3 minutes per treatment	3 minutes per treatment	Similar Note3
Safety and EMC	IEC 60601-1; IEC 60601-1-2 IEC 60601-4-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 IEC 62133-2	IEC 60601-1; IEC 60601-1-2	IEC 60601-1; IEC 60601-1-2 IEC 60601-1-11 IEC 60601-1-6 IEC 60601-2-57 IEC 62133-2	Similar Note4
Biocompatibility	ISO 10993-1	ISO 10993-5	ISO 10993-5	Similar

feature	ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-23	ISO 10993-10 ISO 10993-23	ISO 10993-10	Note4

Comparison in Detail(s):

Note1

Due to different device sizes between the subject and predicate devices, the description of the application site varies, but the actual application site is the same. The difference in applicable location will not raise safety and effective issue.

Note2

The power supply of three devices are very similar but not identical, the IEC60601-1test demonstrated the safety of the power adapter. The subject device shows more information about the battery, with other content remaining the same. The slight difference will not raise safety and effective issue.

Note3

The LED power of these three devices is different. Specifically, the LED power of the subject device is lower than that of the Predicate Device, so the subject device is safer than the Predicate Device. Since the subject device has passed the IEC 60601-2-83 test, this slight difference will not cause safety or effectiveness issues.

The Power Density of the Subject Device is 40 mW/cm² with a Treatment time of 5 minutes, resulting in a cumulative Power Density of 12 J/cm² • min over five minutes. The Power Density of the Predicate Device is 67.7 mW/cm² with a Treatment time of 3 minutes, leading to a cumulative Power Density of 12 J/cm² •min over three minutes. The difference between these two cumulative values is extremely small, which will not cause adverse effects and ensures the effectiveness of the Subject Device.

Note4

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the system come into conclusion.

10. Performance Data:

Non-clinical data:

Non-clinical tests have been conducted to verify that the LED Light Thearpy 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:

- ANSI AAMI ES 60601-1:2005/AMD1:2012/AMD2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests

- IEC/TR 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 60601-1-11:2015/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 60601-2-83:2019 Medical electrical equipment - Part 2-83: Particular requirements for the basicsafety and essential performance of home light therapy equipment
- IEC 62133-2:2017/AMD1:2021 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
- IEC 62471:2016 Photobiological safety of lamps and lamp systems

Biocompatibility Test

The device has been tested for biocompatibility, it complies with the following standards.

- 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 Irritation and Skin Sensitization
- ISO 10993-23:2021, Biological Evaluation of Medical Devices - Part 23: Tests for irritation
- ISO 10993-23:2021 Oral mucosa irritation test

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."

Clinical data: Not applicable.

Summary

Based on the non-clinical and clinical performance as documented in the system development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

11. Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that LED Light Therapy Mask should perform as

intended in the specified use conditions, and all the data demonstrate that the subject devices perform comparably to the predicate device that is currently marketed for the same intended use.

The subject device LED Light Therapy Mask is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K172662, K213024.