June 29, 2026

Guangdong Newdermo Biotech Co., Ltd.
Junyi Xing
Primary Contact
Bldg. 70(C28), # 9 Huateng Rd., Jinshan Village, Shiqi Town, Panyu District
Guangzhou, Guangdong 511450
China

Re: K261052
Trade/Device Name: LED Light Therapy Masks (LED Face Mask Pro (FAC08NA), LED Chest Mask Pro (FAC09NA))
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, ILY
Dated: March 31, 2026
Received: March 31, 2026

Dear Junyi 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 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: 2026.06.29 11:08:01 -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)*
K261052

Device Name
LED Light Therapy Mask

Indications for Use *(Describe)*
The LED Light Therapy Mask (Model: LED Face Mask Pro FAC08NA)is an Over-the-Counter (OTC) device.
1.Red light(630 nm): Intended for treatment of wrinkles.
2.Amber light (605 nm) : Intended for treatment of wrinkles.
3.Red+Near-Infrared(630nm and 830 nm): Intended for treatment of wrinkles.
4. Blue light(415 nm): Intended for treatment of mild to moderate inflammatory acne.
5. Blue and Red (415 nm and 630 nm): Intended for treatment of mild to moderate inflammatory acne.
6. Near-Infrared(830 nm): The device is intended to provide topical heating for the purpose of elevating tissue temperature; 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.

The LED Light Therapy Mask (Model: LED Chest Mask Pro FAC09NA)is an Over-the-Counter (OTC) device.
1.Red light(630 nm): Intended for treatment of wrinkles.
2.Amber light (605 nm) : Intended for treatment of wrinkles.
3.Red+Near-Infrared(630nm and 830 nm): Intended for treatment of wrinkles.
4. Near-Infrared(830 nm): The device is intended to provide topical heating for the purpose of elevating tissue temperature; 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.

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.

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510（K） Summary K261052

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:	February 24, 2026

2. Device name and classification:

Device Name:	LED Light Therapy Mask
Model:	LED Face Mask Pro FAC08NA, LED Chest Mask Pro FAC09NA
Classification Name	Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne Lamp, Infrared, Therapeutic Heating
Product code:	OHS, OLP, 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 device

Sponsor:	Sunglor Technology Co., Ltd.
Device name:	LED Light Therapy Device (SG-FSM, SG-NK, SG-CT)
510(k) Number:	K253073
Regulation Number	21 CFR 878.4810
Classification Name	Light Based Over The Counter Wrinkle Reduction; Lamp, Infrared, Therapeutic Heating
Product Code:	OHS, ILY

2) Reference Device1

Sponsor:	Shenzhen Kaiyan Medical Equipment Co., Ltd.
Device name:	TRUDERMAL Pro (ZLD-390)
510(k) Number:	K251012
Regulation Number	21 CFR 878.4810
Classification Name	Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne Lamp, Infrared, Therapeutic Heating
Product Code:	OHS, OLP, ILY

3) Reference Device2

Sponsor:	Harpar Grace International
Device name:	Shani Darden LED light therapy mask
510(k) Number:	K214103
Regulation Number	21 CFR 878.4810
Classification Name	Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne OHS, OLP
Product Code:	

4) Reference Device3

Sponsor:	Ismart Developments, Ltd.
Device name:	décoLITE LED Device
510(k) Number:	K242382
Regulation Number	21 CFR 878.4810
Classification Name	Light Based over the counter Wrinkle Reduction
Product Code:	OHS

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 uses Light Emitting Diode (LED) energy to treatment of wrinkles, treatment of mild to moderate inflammatory acne, provide topical heating for the purpose of elevating tissue temperature, 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.

There are 4 kinds of light which include Red light (wavelength 630nm), Blue light (wavelength 415nm), Near-Infrared light (wavelength 830nm), Amber light (wavelength 605nm).

There are 2 models of LED Light Therapy Mask, including LED Face Mask Pro FAC08NA, LED Chest Mask Pro FAC09NA.

The product consists of LED Light Therapy Mask, straps (Only LED Face Mask Pro FAC08NA),

remote control, charging cable.

LED Face Mask Pro FAC08NA is designed for facial application, whereas LED Chest Mask Pro FAC09NA is intended for use on the upper chest.

8. Intended Use:

The LED Light Therapy Mask (Model: LED Face Mask Pro FAC08NA)is an Over-the-Counter (OTC) device.

1.Red light(630 nm): Intended for treatment of wrinkles.

2.Amber light (605 nm) : Intended for treatment of wrinkles.

3.Red+Near-Infrared(630nm and 830 nm): Intended for treatment of wrinkles.

4. Blue light(415 nm): Intended for treatment of mild to moderate inflammatory acne.

5. Blue and Red (415 nm and 630 nm): Intended for treatment of mild to moderate inflammatory acne.

6. Near-Infrared(830 nm): The device is intended to provide topical heating for the purpose of elevating tissue temperature; 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.

The LED Light Therapy Mask (Model: LED Chest Mask Pro FAC09NA) is an Over-the-Counter (OTC) device.

1.Red light(630 nm): Intended for treatment of wrinkles.

2.Amber light (605 nm) : Intended for treatment of wrinkles.

3.Red+Near-Infrared(630nm and 830 nm): Intended for treatment of wrinkles.

4. Near-Infrared(830 nm): The device is intended to provide topical heating for the purpose of elevating tissue temperature; 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.

9. Predicate Device Comparison

Table 1 Comparison to Predicate/Reference Device for LED Face Mask Pro FAC08NA, for Face

Item	Subject Device	Predicate Device	Reference Device1	Reference Device2	Comparison Result
Trade name	LED Light Therapy Mask	LED Light Therapy Device (SG-FSM, SG-NK, SG-CT)	TRUDERMAL Pro (ZLD-390)	Shani Darden LED light therapy mask	/
510 (k) number	K261052	K253073	K251012	K214103	/
Manufacturer	Guangdong Newdermo Biotech Co., Ltd	Sunglor Technology Co., Ltd.	Shenzhen Kaiyan Medical Equipment Co., Ltd.	Harpar Grace International	/
Regulation number	21 CFR 878.4810;	21 CFR 878.4810	21 CFR 878.4810;	21 CFR 878.4810	Same
Regulation Name	Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne; Lamp, Infrared, Therapeutic Heating	Light Based Over The Counter Wrinkle Reduction; Lamp, Infrared, Therapeutic Heating	Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne; Lamp, Infrared, Therapeutic Heating	Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne	Similar Note1
Product code	OHS, OLP, ILY	OHS,ILY	OHS, OLP, ILY	OHS, OLP	Similar Note1
Classification	II	II	II	II	Same

Indications for use/ Intended use	The LED Light Therapy Mask (Model: LED Face Mask Pro FAC08NA)is an Over-the-Counter (OTC) device. 1.Red light(630 nm): Intended for treatment of wrinkles. 2.Amber light (605 nm) : Intended for treatment of wrinkles. 3.Red+Near-Infrared(630nm and 830 nm): Intended for treatment of wrinkles. 4. Blue light(415 nm): Intended for treatment of mild to moderate inflammatory acne. 5. Blue and Red (415 nm and 630 nm): Intended for treatment of mild to moderate inflammatory acne. 6. Near-Infrared(830 nm): The device is intended to provide topical heating for the purpose of elevating tissue temperature; 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	The Led Light Therapy Device (Model:SG-FSM) is an Over-the-Counter medical device intended for treatment of wrinkles in the face and decolletage area. Red light: Treatment of wrinkles. Red+Infrared Light: Treatment of wrinkles. Amber light: Treatment of wrinkles. Amber+Infrared Light: Treatment of wrinkles. The Led Light Therapy Device (Model: SG-NK) is an Over-the-Counter medical device intended for treatment of wrinkles in the decolletage area. Red light: Treatment of wrinkles. Red+Infrared Light: Treatment of wrinkles. Amber light: Treatment of wrinkles. Amber+Infrared Light: Treatment of wrinkles. The Led Light Therapy Device (Model:SG-CT) is an Over-the-Counter medical device intended for treatment of wrinkles in the decolletage area. Red light: Treatment of wrinkles. Red+Infrared light: Treatment of wrinkles. Infrared light: Provide topical heating for the purpose of elevating tissue temperature, and to temporarily increase local blood circulation.	TRUDERMAL Pro (Model: ZLD-390) is an over-the-counter(OTC) device that delivering targeted photo therapy using three wavelengths(blue:415nm, red:630nm, Infrared(IR):850nm): Red light: Reduces full-face wrinkles. Blue light: Treats mild to moderate inflammatory acne. IR light: Provides topical heating for the purpose of elevating tissue temperature, temporarily relieving minor muscle and joint pain, arthritis and muscle spasms; relieving stiffness; promoting relaxation of muscle tissues and temporarily increasing local blood circulation. Mixed lights: Red+IR light: Reduces full-face wrinkles. Blue+Red light:Treats mild to moderate inflammatory acne.	The Shani Darden 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 Shani Darden LED light therapy mask 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 wrinkles.	Similar Note2

	blood circulation.				
Location for use	Face	Face and Decolletage (upper chest) Chest	Face and Body	Face	Similar Note3
OTC or prescription	OTC	OTC	OTC	OTC	Same
Power supply	Input: 5V⎓1A; Li-ion Polymer Battery: DC 3.7V, 2000mAh, 7.4Wh	Input: DC 5V, 1ABattery: Li-ion rechargeable battery 3.7V, 3000mAh	Adaptor Input: 100-240Vac, 50-60Hz, 0.8A Output: 12V ⎓ 3A	Electrical Input to power adaptor: 100V-240V. 50/60Hz. Rated at 0.7A. Electrical Output from power adaptor: 12V, 1A	Similar Note4
Power Source	Lithium-Ion Battery (rechargeable)	Lithium-Ion Battery (rechargeable)	100-240Vac	100V-240V	Similar Note4
Light source	LED	LED	LED	LED	same
Wavelengths	605nm; 630nm; 660nm; 830nm; 415nm	SG-FSM: NIR: 850nm (face)and 830nm (upper chest)±10nm; Red: 630nm±10nm; Amber:605nm±10nm; SG-NK: NIR: 830nm±10nm; Red: 630nm±10nm; Amber:605nm±10nm; SG-CT: NIR: 830nm±10nm; Red: 630nm±10nm;	Blue: 415±10nm Red: 630±10nm IR: 850±10nm Mixed light: Blue+Red:415nm+630nm Red+IR:630nm+850nm	Blue: 415nm ± 10nm, Red: 630nm ± 10nm, NIR 830nm ± 10nm.	Similar Note5

Power Density	M1-Red light (630nm): 21mW/cm² ± 20% M2-Blue light (415nm): 19mW/cm² ± 20% M3-Amber light (605nm): 15mW/cm² ± 20% M4-Near-Infrared light (830nm): 4mW/cm² ± 20% M5-Red light (630nm) +Blue light (415nm):40mW/cm² ± 20% M6-Red light (630nm) + Near-Infrared light (830nm): 29mW/cm² ± 20%	Max Irradiance:850/830nm:3±20%mW/cm^2; 630nm:22±20%mW/cm^2; 605nm:14±20%mW/cm^2;	Blue:6-10mW/cm² Red:10-15mW/cm² IR:6-10mW/cm² Mixed light: Blue+Red: 16-20mW/cm² Red+IR:16-20mW/cm²	Blue 28mW/cm^2 Red 16mW/cm^2 Red And Blue Total：44mW/cm^2 Red 18mW/cm^2 NIR 11mW/cm^2 Red And NIR Total：29mW/cm^2	Similar Note6
Treatment time	10 Minutes	10/15/20/25/30minutes	20 min per treatment Acne and Wrinkles: 3-4x weekly; 4 weeks. Pain relief: 3x weekly	10 Minutes	Similar Note6
Safety and EMC	IEC 60601-1; IEC 60601-1-2 IEC 60601-4-2 IEC 60601-1-11 IEC 60601-2-83 IEC 662471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471	IEC 60601-1; IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471	Similar
Biocompatibility feature	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Similar

Comparison in Detail(s):

Note1

The product code/regulation name of the predicate/reference devices includes the product code/regulation name of the subject device. This slight difference will not raise safety and effective issue.

Note2

The indications for use/intended use of the predicate/reference devices includes the indications for use/intended use of the subject device. This slight difference will not raise safety and effective issue.

Note3

The subject device location for use is face (model: LED Face Mask Pro FAC08NA) and upper Chest (model:LED Chest Mask Pro FAC09NA). The predicate device and the reference devices are include the location for use. This slight difference will not raise safety and effective issue.

Note4

The power supply and the power source of four devices are very similar but not identical, the IEC60601-1test demonstrated the safety of the power adapter. The slight difference will not raise safety and effective issue.

Note5

The predicate device and the reference device have fully covered the wavelengths of the subject device. This slight difference will not raise safety and effective issue.(see Note6 for details).

Note6

1. The M1-Red light(630nm, 21mW/cm² ± 20%, 10mins) of the subject device is close to the Red light (630nm, 22mW/cm² ± 20%, 10/15/20/25/30minutes)of the Predicate device. So, it will not raise safety and effective issue.

2. The M2-Blue light(415nm, 19mW/cm² ± 20%, 10mins) of the subject device`s total power density(19×60×10÷1000= 11.4J/cm²) is between the Reference device1(min:6×60×20÷1000= 7.2J/cm² ; max:10×60×20÷1000= 12J/cm²). So, it will not raise safety and effective issue.

3. The M3-Amber light(605nm, 15mW/cm² ± 20%, 10mins) of the subject device is close to the Amber light (630nm, 14mW/cm² ± 20%, 10/15/20/25/30minutes)of the Predicate device. So, it will not raise safety and effective issue.

4. The M4-Near-Infrared light(830nm, 4mW/cm² ± 20%, 10mins) of the subject device is close to the Max Irradiance (830/850nm, 3mW/cm² ± 20%, 10/15/20/25/30minutes)of the Predicate device. So, it will not raise safety and effective issue.

5. The M5-Red light and Blue light(630nm+415nm, 40mW/cm² ± 20%, 10mins) is close to the Red light and Blue light(630nm+415nm, 44mW/cm² , 10mins) of

the Reference device2. So, it will not raise safety and effective issue.

6. The M6-Red light and Near-Infrared light(630+830nm, 29mW/cm² ±20%, 10mins) as same as the Red light and Near-Infrared light(630nm+830nm,29mW/cm² , 10mins) of the Reference device2. So, it will not raise safety and effective issue.

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.

Table 2 Comparison to Predicate/Reference Device for LED Chest Mask Pro FAC09NA,

Item	Subject Device	Predicate Device	Reference Device3	Comparison Result
Trade name	LED Light Therapy Mask	LED Light Therapy Device (SG-FSM, SG-NK, SG-CT)	décoLITE LED Device	/
510 (k) number	K261052	K253073	K242382	/
Manufacturer	Guangdong Newdermo Biotech Co.,Ltd	Sunglor Technology Co., Ltd.	Ismart Developments, 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; Over-The-Counter Powered Light Based Laser For Acne; Lamp, Infrared, Therapeutic Heating	Light Based Over The Counter Wrinkle Reduction ; Lamp, Infrared, Therapeutic Heating	Light Based Over The Counter Wrinkle Reduction	Similar Note8
Product code	OHS, OLP, ILY	OHS,ILY	OHS	Similar Note8
Classification	II	II	II	Same

Indications for use/ Intended use	The LED Light Therapy Mask (Model: LED Chest Mask Pro FAC09NA)is an Over-the-Counter (OTC) device. 1.Red light(630 nm): Intended for treatment of wrinkles. 2.Amber light (605 nm) : Intended for treatment of wrinkles. 3.Red+Near-Infrared(630nm and 830 nm): Intended for treatment of wrinkles. 4. Near-Infrared(830 nm): The device is intended to provide topical heating for the purpose of elevating tissue temperature; 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.	The Led Light Therapy Device (Model:SG-FSM) is an Over-the-Counter medical device intended for treatment of wrinkles in the face and decolletage area. Red light: Treatment of wrinkles. Red+Infrared Light: Treatment of wrinkles. Amber light: Treatment of wrinkles. Amber+Infrared Light: Treatment of wrinkles. The Led Light Therapy Device (Model: SG-NK) is an Over-the-Counter medical device intended for treatment of wrinkles in the decolletage area. Red light: Treatment of wrinkles. Red+Infrared Light: Treatment of wrinkles. Amber light: Treatment of wrinkles. Amber+Infrared Light: Treatment of wrinkles. The Led Light Therapy Device (Model:SG-CT) is an Over-the-Counter medical device intended for treatment of wrinkles in the decolletage area. Red light: Treatment of wrinkles. Red+Infrared light: Treatment of wrinkles. Infrared light: Provide topical heating for the purpose of elevating tissue temperature, and to temporarily increase local blood circulation.	The décoLITE LED device is an over-the-counter device that is intended for the use in the treatment of wrinkles in the decolletage area.	Similar Note9
Location for use	Decolletage (upper chest)	Face and Decolletage (upper chest) Chest	Decolletage (upper chest)	Similar Note10
OTC or prescription	OTC	OTC	OTC	Same
Power supply	Input: 5V⎓1A; Li-ion Polymer Battery: DC 3.7V, 2000mAh, 7.4Wh	Input: DC 5V, 1ABattery: Li-ion rechargeable battery 3.7V, 3000mAh	not shown	Similar Note11
Power Source	Lithium-Ion Battery (rechargeable)	Lithium-Ion Battery (rechargeable)	Lithium-Ion Battery (rechargeable)	Similar Note11

Light source	LED	LED	LED	same
Wavelengths	605nm; 630nm; 660nm; 830nm;	SG-FSM: NIR: 850nm (face)and 830nm (upper chest)±10nm; Red: 630nm±10nm; Amber:605nm±10nm; SG-NK: NIR: 830nm±10nm; Red: 630nm±10nm; Amber:605nm±10nm; SG-CT: NIR: 830nm±10nm; Red: 630nm±10nm;	Red: 630nm±10nm NIR: 830nm±10nm	Similar Note12
Power Density	M1-Red light (630nm): 21mW/cm² ± 20% M2-Amber light (605nm): 15mW/cm² ± 20% M3-Near-Infrared light (830nm): 4mW/cm² ± 20% M4-Red light (630nm) + Near-Infrared light (830nm): 29mW/cm² ± 20%	Max Irradiance:850/830nm:3±20%mW/cm^2; 630nm:22±20%mW/cm^2; 605nm:14±20%mW/cm^2;	30mW/cm^2 total	Similar Note13
Treatment time	The session begins and lasts for 10 minutes for modes M1, M2,M3,M4.	10/15/20/25/30minutes	600 seconds (10 minutes)	Similar Note13
Safety and EMC	IEC 60601-1; IEC 60601-1-2 IEC 60601-4-2 IEC 60601-1-11 IEC 60601-2-83 IEC 662471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471	IEC 60601-1; IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	Similar
Biocompatibility feature	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-23	Similar

Comparison in Detail(s):

Note8

The product code/regulation name of the predicate/reference devices includes the product code/regulation name of the subject device. This slight difference will not raise safety and effective issue.

Note9

The indications for use/intended use of the predicate/reference devices includes the indications for use/intended use of the subject device. This slight difference will not raise safety and effective issue.

Note10

The subject device location for use is face(model: LED Face Mask Pro FAC08NA) and upper Chest (model:LED Chest Mask Pro FAC09NA). The predicate device and the reference devices are include the location for use. This slight difference will not raise safety and effective issue.

Note11

The power supply and the power source of four devices are very similar but not identical, the IEC60601-1test demonstrated the safety of the power adapter. The slight difference will not raise safety and effective issue.

Note12

The predictive device and the reference device have fully covered the wavelengths of the subject device. This slight difference will not raise safety and effective issue.(see Note13 for details).

Note13

1. The M1-Red light(630nm, 21mW/cm² ± 20%, 10mins) of the subject device is close to the Red light (630nm, 22mW/cm² ± 20%, 10/15/20/25/30minutes)of the Predicate device. So, it will not raise safety and effective issue.
2. The M2-Amber light(605nm, 15mW/cm² ± 20%, 10mins) of the subject device is close to the Amber light (630nm, 14mW/cm² ± 20%, 10/15/20/25/30minutes)of the Predicate device. So, it will not raise safety and effective issue.
3. The M3-Near-Infrared light(830nm, 4mW/cm² ± 20%, 10mins) of the subject device is close to the Max Irradiance (830/850nm, 3mW/cm² ± 20%, 10/15/20/25/30minutes)of the Predicate device. So, it will not raise safety and effective issue.
4. The M4-Red light and Near-Infrared light(630+830nm, 29mW/cm² ±20%, 10mins) is close to the Red light and Near-Infrared light(630nm+830nm, 30mW/cm², 10mins) of the Reference device3. So, it will not raise safety and effective issue.

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 Beauty LED 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

Software Verification and Validation Testing

Software verification and validation testing were conducted, and Basic 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 supports the safety of the device and the hardware and software verification, and validation demonstrates that LED Light Therapy Mask should perform as intended in the specified use conditions. The device has been tested as described above to show that the device can be used safely and effectively. The subject device LED Light Therapy Mask is as safe, as effective, and performs as well as than the legally marketed predicated devices (K253073, K251012, K214103 and K242382.)