June 18, 2026

Guangdong Newdermo Biotech Co., Ltd.
Junyi Xing
Certificate Engineer
Contact Address

Re: K260946
Trade/Device Name: LED Light Therapy Mask (K9C-TK, K9C-K, K9P-YK, K9P-K, FM-03BK, FM-09K)
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: March 23, 2026
Received: March 23, 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: 2026.06.18 16:18:07 -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)*
K260946

Device Name
LED Light Therapy Mask (K9C-TK, K9C-K, K9P-YK, K9P-K, FM-03BK, FM-09K)

Indications for Use *(Describe)*
The LED Light Therapy Mask adopts the latest LED light therapy technology, combining 6 kinds of Model: K9C-TK, K9C-K, K9P-YK, K9P-K, FM-03BK, FM-09K.
The LED Light Therapy Mask (Model:K9C-TK) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.
1.Deep Red and Infrared light (660nm + 850nm): Intended for treatment of wrinkles.
2.Red light and Near-Infrared light (630nm + 830nm): Intended for treatment of wrinkles.
3.Amber light(605nm): Intended for treatment of wrinkles.
4. Blue light and Red light (415nm + 630nm): Intended for treatment of mild to moderate inflammatory acne.
5.Blue light(415nm): Intended for treatment of mild to moderate inflammatory acne.

The LED Light Therapy Mask (Models:K9C-K, K9P-YK, K9P-K) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.
1.Deep Red and Infrared light (660nm + 850nm): Intended for treatment of wrinkles.
2.Red light and Near-Infrared light (630nm + 830nm): Intended for treatment of wrinkles.
3.Blue light and Red light (415nm + 630nm): Intended for treatment of mild to moderate inflammatory acne.
4.Blue light(415nm): Intended for treatment of mild to moderate inflammatory acne.

The LED Light Therapy Mask(Model: FM-03BK) is an Over-the-Counter (OTC) device intended for treatment of wrinkles.
1.Red light (630nm): Intended for treatment of wrinkles.
2.Red light and Near-Infrared light (630nm + 830nm): Intended for treatment of wrinkles.

The LED Light Therapy Mask (Model: FM-09K) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.
1.Red light (630nm): Intended for treatment of wrinkles.
2.Red light and Near-Infrared light (630nm + 830nm): Intended for treatment of wrinkles.
3.Blue light and Red light (415nm + 630nm): Intended for treatment of mild to moderate inflammatory acne.
4.Blue light(415nm): Intended for 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.

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510（K）Summary

K260946

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:	June 10, 2026

2. Device name and classification:

Device Name:	LED Light Therapy Mask
Model:	K9C-TK, K9C-K, K9P-YK, K9P-K, FM-03BK, FM-09K
Classification Name	Light Based Over The Counter Wrinkle Reduction Over-The-Counter Powered Light Based Laser For Acne
Product code:	OHS, OLP
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):

Predicate #	Sponsor	Device name	510(k) Number	Regulation Number	Product Code
Predicate device1	Harpar Grace International	Shani Darden LED light therapy mask	K214103	21 CFR 878.4810	OLP, OHS
Reference Device1	Therabody, Inc.	TheraFace Mask	K230293	21 CFR 878.4810	OHS, OLP
Reference Device2	Shenzhen Qianyu Technology Co., Ltd.	Wrinkle Treatment Device (JM2)	K240360	21 CFR 878.4810	OHS
Reference Device3	Sunglor Technology Co., Ltd.	LED Light Therapy Device (SG-FSM, SG-NK, SG-CT)	K253073	21 CFR 878.4810	OHS, ILY
Predicate device2	Shenzhen Kaiyan Medical Equipment Co., Ltd..	TRUDERMAL Pro (ZLD-390)	K251012	21 CFR 878.4810	OHS, OLP, ILY
Reference Device4	Ismart Developments, Ltd.	déCoLITE LED Device	K242382	21 CFR 878.4810	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 wearable LED photo therapy device. LED Light Therapy Mask intended for treatment of wrinkles and mild to moderate inflammatory acne. LED Light Therapy Mask is consisting of mask, controller, USB cable and straps. There are 6 models of LED Light Therapy Mask, including K9C-TK, K9P-YK, K9C-K, K9P-K, FM-03BK, FM-09K.

There are 6 kinds of light which include Red light (wavelength 630nm), Deep Red light (wavelength 660nm), Blue light (wavelength 415nm), Amber Light (wavelength 605nm), Near-Infrared light (wavelength 830nm), Infrared light (wavelength 850nm).

For the FM-03BK model, the available modes are Red Light only (630 nm) and Red + Near-Infrared Light (630nm+830nm).

8. Indications for Use:

The LED Light Therapy Mask adopts the latest LED light therapy technology, combining 6 kinds of Model: K9C-TK, K9C-K, K9P-YK, K9P-K, FM-03BK, FM-09K.

The LED Light Therapy Mask (Model: K9C-TK) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.

1.Deep Red and Infrared light (660nm + 850nm): Intended for treatment of wrinkles.
2.Red light and Near-Infrared light (630nm + 830nm): Intended for treatment of wrinkles.
3.Amber light (605nm): Intended for treatment of wrinkles.
4. Blue light and Red light (415nm + 630nm): Intended for treatment of mild to moderate inflammatory acne.
5.Blue light(415nm): Intended for treatment of mild to moderate inflammatory acne.

The LED Light Therapy Mask (Models: K9C-K, K9P-YK, K9P-K) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.
1.Deep Red and Infrared light (660nm + 850nm): Intended for treatment of wrinkles.
2.Red light and Near-Infrared light (630nm + 830nm): Intended for treatment of wrinkles.
3.Blue light and Red light (415nm + 630nm): Intended for treatment of mild to moderate inflammatory acne.
4.Blue light(415nm): Intended for treatment of mild to moderate inflammatory acne.

The LED Light Therapy Mask (Model: FM-03BK) is an Over-the-Counter (OTC) device intended for treatment of wrinkles.
1.Red light (630nm): Intended for treatment of wrinkles.
2.Red light and Near-Infrared light (630nm + 830nm): Intended for treatment of wrinkles.

The LED Light Therapy Mask (Model: FM-09K) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.
1.Red light (630nm): Intended for treatment of wrinkles.
2.Red light and Near-Infrared light (630nm + 830nm): Intended for treatment of wrinkles.
3.Blue light and Red light (415nm + 630nm): Intended for treatment of mild to moderate inflammatory acne.
4.Blue light(415nm): Intended for treatment of mild to moderate inflammatory acne.

9. Predicate Device Comparison

Table1 Comparison to Predicate/Reference Device for K9C-TK, K9C-K, K9P-YK, K9P-K, for Face

Item	Subject Device	Predicate Device1	Reference Device1	Reference Device2	Reference Device3	Comparison Result
Trade name	LED Light Therapy Mask	Shani Darden LED light therapy mask	TheraFace Mask	Wrinkle Treatment Device (JM2)	LED Light Therapy Device (SG-FSM, SG-NK, SG-CT)	/
510 (k) number	K260946	K214103	K230293	K240360	K253073	/
Manufacturer	Guangdong Newdermo Biotech Co., Ltd.	Harpar Grace International	Therabody, Inc.	Shenzhen Qianyu Technology Co., Ltd.	Sunglor Technology Co., Ltd.	/
Regulation number	21 CFR 878.4810	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	Light Based Over The Counter Wrinkle Reduction, Over-The-Counter Powered Light Based Laser For Acne	Light Based Over The Counter Wrinkle Reduction, Over-The-Counter Powered Light Based Laser For Acne	Light Based Over The Counter Wrinkle Reduction	Light Based Over The Counter Wrinkle Reduction, Lamp, Infrared, Therapeutic Heating	Similar Note1
Product code	OHS, OLP	OHS, OLP	OHS, OLP	OHS	OHS, ILY	Similar Note1
Classification	II	II	II	II	II	Same

Indications for use/ Intended use	See Indications for Use Section	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.	Red Light is intended to treat full face wrinkles. Blue Light is intended to treat mild to moderate inflammatory acne. Red + Infrared Light is intended to treat full face wrinkles.	The wrinkle treatment device (model: JM2) is an Over-The-Counter (OTC) light based device intended for the use in treating full-face wrinkles.	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.	Similar Note2
Location for use	Face and Body	Face	Face	Face	Face, Body	Similar Note3

OTC or prescription	OTC	OTC	OTC	OTC	OTC	Same
Power supply	Input:DC 5.0V , 1A； Li-ion Polymer Battery: DC 3.7V, 2450mAh, 9.065Wh	Electrical Input to power adaptor: 100V-240V. 50/60Hz. Rated at 0.7A. Electrical Output from power adaptor: 12V, 1A	5-15V DC 2.5A max powered by 2 Li-Ion Batteries 3.7V 1500mAh) is charged via Universal USB charger cord or fast charger adaptor	Not display	Input: DC 5V, 1ABattery: Li-ion rechargeable battery 3.7V, 3000mAh	Similar Note4
Power Source	Lithium-Ion Battery (rechargeable)	100V-240V	Lithium-Ion Battery (rechargeable)	Lithium-Ion Battery (rechargeable)	Lithium-Ion Battery (rechargeable)	Similar Note4
Light source	LED	LED	LED	LED	LED	same
Wavelengths	Red light: 630nm Deep Red light: 660nm; Blue light: 415nm; Amber Light: 605nm (Only K9C-TK); Near-Infrared light: 830nm; Infrared light: 850nm.	Blue: 415nm ± 10nm, Red: 630nm ± 10nm, NIR 830nm ± 10nm.	Red： 633 ± 10nm Blue: 415 ± 10nm Red + IR: 633 ± 10nm/830 ± 10nm	660 ± 20nm 850 ± 20nm	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;	Similar Note5

Power Density	Deep Red light+Infrared light: 40mw/cm^2 Blue light: 19mw/cm^2 Amber light: 15mw/cm^2 (Only K9C-TK) Red light+Near-Infrared light: 29mw/cm^2 Red light+Blue light: 44mw/cm^2	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	Red: 73 ± 5mW/cm^2; Blue: 64 ± 5mW/cm^2 Red + IR: 73 ± 5mW/cm^2/55 ± 5mW/cm^2	40/70/100mW/cm^2	Max Irradiance:850/830nm:3±20%mW/cm^2; 630nm:22±20%mW/cm^2; 605nm:14±20%mW/cm^2;	Similar Note6

Treatment time	Manual Mode: 10minutes Automatic Mode: 15minutes	10 Minutes	LED: 3 minutes each light mode for a total of 9 minutes per treatment, recommended to use 2 to 5 times per week. Vibration: accompanies LED treatments or can be used without LED's active. 3 vibration patterns, 5 minutes each, for a total of 15 minutes. During blue light treatment mode, vibration is not active around the eyes. Vibration is included for a more relaxing experience.	Not displayed	10/15/20/25/30minutes	Similar Note6
Safety and EMC	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	EC 60601-1; IEC 60601-1-2 IEC 60601-1-11 IEC 60825-1	IEC 60601-1; IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471	Similar Note7

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: K9C-TK\ K9P-YK\ K9C-K\ K9P-K) and body(model: FM-03BK\ FM-09K). 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 of the devices are very similar but not identical, the IEC60601-1test demonstrated the safety of the power source. 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.

Note5

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 Note6 for details)

Note6

1. The Red light + Near-Infrared light mode and the Red light + Blue light mode of the subject device as same as the predicate device1;
2. The Blue light mode of the subject device`s total power density(19×60×10÷1000=11.4J/cm²) as same as the reference device1(64×60×3÷1000=11.52J/cm$^{2)}$, so this slight deference will not raise safety and effective issue;
3. The Deep Red light + Infrared light mode of the subject devices same as the reference device2;
4. The Amber light mode(wavelength 605nm, for face)`s total power density(15×60×10÷1000= 9J/cm²) is between the reference device4(min:14×60×10÷1000= 8.4J/cm² ; max:14×60×30÷1000= 25.2J/cm²). So, it will not raise safety and effective issue.

Note7

The subject device complies with more laws, making it safer compared to the predicate device.

The definition Of HOME LIGHT THERAPY EQUIPMENT in IEC 60601-2-83 standard is broader than the corresponding definition of light-source equipment in IEC 60601-2-57 and includes both eye-mediated and skin-mediated photo biological effects, which can be visual and non-visual as explained in the introduction. The definition is restricted to equipment intended to be used.

Table2 Comparison to Predicate/Reference Device for FM-03BK, FM-09K, for Body

Item	Subject Device	Predicate Device2	Reference Device3	Reference Device4	Comparison Result
Trade name	LED light therapy mask	TRUDERMAL Pro (ZLD-390)	LED Light Therapy Device (SG-FSM, SG-NK, SG-CT)	décoLITE LED Device	/
510 (k) number	K260946	K251012	K253073	K242382	/
Manufacturer	Guangdong Newdermo Biotech Co., Ltd.	Shenzhen Kaiyan Medical Equipment Co., Ltd.	Sunglor Technology Co., Ltd.	Ismart Developments, Ltd.	/
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	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	OHS, OLP, ILY	OHS, ILY	OHS	Similar Note8
Classification	II	II	II	II	Same

Indications for use/ Intended use	See Indications for Use Section	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 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	Face and Body	Face, Body	Face, Body	Body	Similar Note10
OTC or prescription	OTC	OTC	OTC	OTC	Same

Power supply	Input:DC 5.0V, 1A； Li-ion Polymer Battery: DC 3.7V, 2450mAh, 9.065Wh	Adaptor Input: 100-240Vac, 50-60Hz, 0.8A Output: 12V ⎓ 3A	Input: DC 5V, 1ABattery: Li-ion rechargeable battery 3.7V, 3000mAh	not shown	Similar Note4
Power Source	Lithium-Ion Battery (rechargeable)	100-240Vac	Lithium-Ion Battery (rechargeable)	Lithium-Ion Battery (rechargeable)	Similar Note11
Light source	LED	LED	LED	LED	same
Wavelengths	Red light: 630nm Deep Red light:660nm Blue light: 415nm, Near-Infrared light:830nm, Infrared light (wavelength 850nm).	Blue: 415±10nm Red: 630±10nm IR: 850±10nm Mixed light: Blue+Red:415nm+630nm Red+IR:630nm+850nm	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	1. Deep Red light + Infrared light(wavelengths: 660nm + 850nm):40mw/cm^2(Only K9C-TK \ K9P-YK \ K9C-K \ K9P-K) 2.Blue light(415nm): 19mw/cm^2(Only K9C-TK \ K9P-YK \ K9C-K \ K9P-K) or 15mw/cm^2(Only FM-09K) 3.Amber Light (wavelength 605nm): 15mw/cm^2 (Only K9C-TK) 4.Red light + Near-Infrared light(wavelength 630nm + 830nm): 29mw/cm^2 5.Red light + Blue light(wavelength 630nm + 415nm): 44mw/cm^2(Only K9C-TK \ K9P-YK \ K9C-K \ K9P-K) or 36mw/cm^2(Only FM-09K) 6.Red light(wavelength 630nm): 21mw/cm^2(Only FM-03BK \ FM-09K)	Blue:6-10mW/cm^2 Red:10-15mW/cm^2 IR:6-10mW/cm^2 Mixed light: Blue+Red: 16-20mW/cm^2 Red+IR:16-20mW/cm^2	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	Manual Mode: 10minutes Automatic Mode: 15minutes	20 min per treatment Acne and Wrinkles: 3-4x weekly; 4 weeks. Pain relief: 3x weekly	10/15/20/25/30minutes	600 seconds (10 minutes)	Similar Note13
Safety and EMC	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 60601-2-83 IEC 62471	IEC 60601-1; IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	Similar Note14

Note8

The product code/regulation name/regulation number 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. t. This slight difference will not raise safety and effective issue.

Note10

The subject device location for use is face(model: K9C-TK\ K9P-YK\ K9C-K\ K9P-K) and body(model: FM-03BK\ FM-09K). 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 of the devices are very similar but not identical, the IEC60601-1test demonstrated the safety of the power source. 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.

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

1.1 The Blue light mode of the subject device`s total power density(15 × 60 × 10 ÷1000=9J/cm²) is between the predicate device2(min: 6 × 60 × 20 ÷1000= 7.2 J/cm²;max:10 × 60 × 20 ÷1000= 12 J/cm²), so this slight deference will not raise safety and effective issue;

1.2 The Red light + Blue light mode of the subject device`s total power density (36 × 60 × 10 ÷1000= 21.6 J/cm²) is between the predicate device2(min: 16 × 60 × 20 ÷1000= 19.2 J/cm²;max:20 × 60 × 20 ÷1000= 24 J/cm²); so this slight deference will not raise safety and effective issue;

2. The Red light mode of the subject device as same as the reference device3.

3. The Red light + Near-Infrared light mode of the subject device as same as the reference device4.

Note14

The subject device complies with more laws, making it safer compared to the predicate device.

The definition Of HOME LIGHT THERAPY EQUIPMENT in IEC 60601-2-83 standard is broader than the corresponding definition of light-source equipment in IEC 60601-2-57 and includes both eye-mediated and skin-mediated photo biological effects, which can be visual and non-visual as explained in the introduction. The definition is restricted to equipment intended to be used.

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 documentation was

provided as recommended by FDA's 2023 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

Based on comparing to predicate devices and reference devices, the proposed device of K9C-TK, K9C-K, K9P-YK, K9P-K, FM-03BK and FM-09K are determined to be Substantially Equivalent (SE) to the predicate devices, in respect of safety and effectiveness.