August 21, 2025

Shenzhen Fittop Health Technology Co., Ltd.
℅ Youshan Gong
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road, Nanshan District
Shenzhen, Guangdong 518052
China

Re: K251588
Trade/Device Name: LED Light Therapy Mask (FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910)
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: May 16, 2025
Received: May 23, 2025

Dear Youshan Gong:

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: 2025.08.21 14:31:03 -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)*
K251588

Device Name
LED Light Therapy Mask (FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910)

Indications for Use *(Describe)*
The LED Light Therapy Mask (Model: FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.

FCM902, FCM905, FCM906, FCM908:
a.Red light: Treatment of full-face wrinkles.
b.Blue+Infrared light: Treatment of mild to moderate inflammatory acne.
c.Yellow+Infrared light: Treatment of full-face wrinkles.

11-001-RBMASK:
a.Red+Infrared light: Treatment of full-face wrinkles.
b.Blue light: Treatment of mild to moderate inflammatory acne.

FCM910:
a.Red+Infrared light: Treatment of full-face wrinkles.
b.Blue light: Treatment of mild to moderate inflammatory acne.
c.Yellow+Infrared light: 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 of K251588

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	Shenzhen Fittop Health Technology Co., Ltd.
Address:	3, 6, 8/F, BLDG 3, No.7, LangFeng Road, Xinshi, Community, Dalang, Longhua District, Shenzhen, Guangdong, 518000, China
Contact person:	Sandy Lee
Position:	Vice president
Phone number:	+86-13828835685
Email:	info@fittop.com
Contact person:	Sandy Lee
Date of summary prepared:	2025-8-19

(2) Reason for the submission

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

(3) Proprietary name of the device

Trade name/model:	LED Light Therapy Mask/Model: FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910
Regulation name:	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared, Therapeutic Heating(ILY)
Regulation number:	21 CFR 878.4810, 21 CFR 890.5500
Product code:	OHS, OLP, ILY
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(4) Predicate devices

- **Primary Predicate device 1**

Sponsor	Shenzhen Kaiyan Medical Equipment Co., Ltd
Device Name and Model	CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (MK-90C, MK-90M, MK66RB-F, MK-90N)
510(k) Number	K242593
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810

Regulation Class	II

- **Predicate device 2**

Sponsor	Dongguan Boyuan Intelligent Technology Co., Ltd.
Device Name and Model	LED Light Therapy Device (KFB290, KFB291, KFB265, KFB293)
510(k) Number	K241857
Product Code	OHS, OLP, ILY
Regulation Number	21 CFR 878.4810, 21 CFR 890.5500
Regulation Class	II

- **Predicate device 3**

Sponsor	SharkNinja Operating, LLC
Device Name and Model	CryoGlow (FW3XXXX)
510(k) Number	K242796
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	II

- **Predicate device 4**

Sponsor	Shenzhen SUNGPO HI-TECH Electronic Co.,Ltd
Device Name and Model	LED Facial Mask/MZ-01, NEWKEY-01, SP-FM-01
510(k) Number	K230351
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	II

- **Predicate device 5**

Sponsor	Shenzhen Kaiyan Medical Equipment Co., Ltd
Device Name and Model	Q-Rejuvalight Pro Facewear (Model: P19-0023)
510(k) Number	K230042
Product Code	OHS, OLP
Regulation Number	21 CFR 878.4810
Regulation Class	II

(5) Description/ Design of device:

The LED Light Therapy Mask (FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK,

FCM910) adopts light emitting diodes (LED) in the red (630nm ±5nm) , infrared (880nm±5nm) and blue (415±5nm) spectrum to irradiate on the face to realize its therapeutic effect.

For FCM902, FCM905, FCM906, FCM908 and FCM910, it also contain yellow (590±5nm) spectrum and green (520±5nm) spectrum.

The LED Light Therapy Mask adopts the form of a mask that contains LEDs on the inner surface of the main unit. A controller is connected to the main unit to control the device, such as turn on/off the device, switch mode (LED color). To use the device, user should place the mask over the face and use the controller to operate. The device will automatically turn off after each treatment. To prevent irradiation of LED lights to eyes during the treatment, LED Light Therapy Mask has incorporated protective eye-shield which blocks light energy from LEDs.

a. Red light: Treatment of full-face wrinkles.
b. Blue+Infrared light: Treatment of mild to moderate inflammatory acne.
c. Yellow+Infrared light: Treatment of full-face wrinkles.
d. Green Light: light in wavelength 520nm(±5nm). Green light makes users feel like they are outside in a green world, which may make users relax, which has no medical therapeutic effect.
e. Red+Infrared light: Treatment of full-face wrinkles.
f. Blue light: Treatment of mild to moderate inflammatory acne.

(6) Indications for use:

The LED Light Therapy Mask (Model: FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.

FCM902, FCM905, FCM906, FCM908:

a.Red light: Treatment of full-face wrinkles.

b.Blue+Infrared light: Treatment of mild to moderate inflammatory acne.

c.Yellow+Infrared light: Treatment of full-face wrinkles.

11-001-RBMASK:

a.Red+Infrared light: Treatment of full-face wrinkles.

b.Blue light: Treatment of mild to moderate inflammatory acne.

FCM910:

a.Red+Infrared light: Treatment of full-face wrinkles.

b.Blue light: Treatment of mild to moderate inflammatory acne.

c.Yellow+Infrared light: Treatment of full-face wrinkles.

(7) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
LED Light Therapy Mask (FCM902)	Silicone, ABS, PVC, Metal	Surface-contacting device: Intact skin	Less than 24 hours
LED Light Therapy Mask (FCM905, FCM906, FCM908)	Silicone, ABS, Metal, PC		
LED Light Therapy Mask (11-001-RBM ASK)	ABS, Silicone, Metal; Belt : Polyamides (PA)		
LED Light Therapy Mask (FCM910)	Silicone, ABS, PC, Metal		

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to "Biocompatibility Discussion".

(8) Technological characteristics and substantial equivalence:

The LED Light Therapy Mask is intended to use LED light for the treatment of wrinkles and mild to moderate inflammatory acne.

Based on FDA Medical Device Database, we can find its similar devices. And we adopt K242593 as its primary predicate device and K241857, K242796, K230351 and K230042 as its predicate devices. Through the comparisons, we come to a conclusion that these devices have the same intended use, similar technological characteristics and principles of operation.

The details are as follows:

Item	Subject device K251588	Primary Predicate device 1 K242593	Predicate device 2 K241857	Predicate device 3 K242796	Predicate device 4 K230351	Predicate device 5 K230042	Remark
Trade name	LED Light Therapy Mask/ Model: FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910	CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (MK-90C, MK-90N)	LED Light Therapy Device (KFB290, KFB291)	CryoGlow (FW3XXXX)	LED Facial Mask/ MZ-01, NEWKEY-01, SP-FM-01	Q-Rejuvalight Pro Facewear	/
510 (k) number	K251588	K242593	K241857	K242796	K230351	K230042	/
Manufacturer	Shenzhen Fittop Health Technology Co., Ltd.	Shenzhen Kaiyan Medical Equipment Co., Ltd	Dongguan Boyuan Intelligent Technology Co., Ltd.	SharkNinja Operating, LLC	Shenzhen SUNGPO HI-TECH Electronic Co.,Ltd	Shenzhen Kaiyan Medical Equipment Co., Ltd	/
Regulation number	21 CFR 878.4810, 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810, 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Regulation name	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared, Therapeutic Heating(ILY)	Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared, Therapeutic Heating(ILY)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)	Same
Product code	OHS, OLP, ILY	OHS, OLP	OHS, OLP, ILY	OHS, OLP	OHS, OLP	OHS, OLP	Same
Class	II	II	II	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 wrinkles and mild to moderate inflammatory acne. FCM902, FCM905, FCM906, FCM908: g. Red light: Treatment of full-face wrinkles. h. Blue+Infrared light: Treatment of mild to moderate inflammatory acne. i. Yellow+Infrared light: Treatment of full-face wrinkles. 11-001-RBMASK: a. Red+Infrared light: Treatment of full-face wrinkles.	For MK-90C: The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK-90C) is an over the counter device, specifically indicated to treat mild to moderate acne vulgaris of the face and use in the treatment of full-face wrinkles. For MK-90N: The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK-90N) is an over the counter device, is	KFB290, KFB291: a. Red light: Treatment of full-face wrinkles. b. Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily	The CryoGlow LED mask emits energy in the red and infrared light spectrum for the treatment of fine lines and wrinkles and in the red, blue, and infrared light spectrum for the treatment of mild-to-moderate inflammatory acne.	LED Facial Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	The QRejuvalight Pro Facewear (Model: P19- 0023) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.	Similar **Note 1**

Item	Subject device K251588	Primary Predicate device 1 K242593	Predicate device 2 K241857	Predicate device 3 K242796	Predicate device 4 K230351	Predicate device 5 K230042	Remark
	b. Blue light: Treatment of mild to moderate inflammatory acne. FCM910: a. Red+Infrared light: Treatment of full-face wrinkles. b. Blue light: Treatment of mild to moderate inflammatory acne. c. Yellow+Infrared light: Treatment of full-face wrinkles.	generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles.	increase local blood circulation. c. Red+Infrared Light: Treatment of full-face wrinkles. d. Amber light: Treatment of full-face wrinkles. e. Blue light: Treatment of mild to moderate inflammatory acne. f. Mixed light(Red+Blue +Infrared): Treatment of mild to moderate inflammatory acne.				
Location for use	Face	Face	Face	Face	Face	Face	Same
OTC or prescription	OTC	OTC	OTC	OTC	OTC	OTC	Same
Power supply	Input: 100 -240 V ~ 50 / 60 Hz Li-ion Polymer Battery (FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK): 2850mAh Li-ion Polymer Battery (FCM910): 1000mAh	MK-90C and MK-90N: 3.7Vdc, 5200mAh，19.24Wh Lithium battery	Input: 100 -240 V, 50 / 60 Hz Output: 5V, 1A Lithium ion battery: 1300mAh	2 Li-Ion Batteries 3.6V, 2350 mAh total, charged by USB-A to USB-C charging cord to USB-A charging block	An external adapter Input: AC 100-240V 50-60Hz 0.2A Output: DC 12V 0.5A	Input: 5V, 50/60Hz, 2A Li-ion Polymer Battery: 3.7V, 600mAh, 2.22Wh	Different **Note 2**
Light source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Same
Wavelength	630nm ±5nm visible red light; 880nm±5nm non-visible red light; 415±5nm blue light; 590±5nm yellow light	MK-90C Mode 1: Red + Infrared (633nm+830nm) Mode 2: Blue + Red (415nm+633nm) Mode 3: Yellow + Infrared (590nm+830nm) MK-90N Mode: Yellow + Infrared (590nm+830nm)	635nm ± 5nm visible red light; 850nm±5nm Invisible red light; 465±5nm blue light; 605±5nm amber light	630 ±10nm, 830 ± 10 nm, 415 ±10nm	625nm±5nm, 465nm±5nm, 605±5nm	630nm, 880nm, 415nm 605nm, 660nm,	Same
LED power	**FCM902, FCM905, FCM906, FCM908:** 1) "R" (Red) (630nm): low: 25mW/cm²,	415nm: 25±5mW/cm²; 633nm: 20±5mW/cm²;	Red: 25mW/cm² ; IR: 3mW/cm² ;	**Skin Sustain:** Blue 59.8 ± 7 mW/cm²,	Blue:15~63mW/cm² Red: 31~75mW/cm²	Single wavelength: 605nm:	Similar **Note 3**

Item	Subject device K251588	Primary Predicate device 1 K242593	Predicate device 2 K241857	Predicate device 3 K242796	Predicate device 4 K230351	Predicate device 5 K230042	Remark
	medium: 35mW/cm², high: 40mW/cm² 2) "Y+NIR"(Yellow+NIR) (590nm+880nm) : Yellow: low:5mW/cm², medium: 7mW/cm², high: 10mW/cm²; NIR:10mW/cm² 3) "G"(Green) :(520nm) : low: 3mW/cm², medium: 4mW/cm², high: 5mW/cm² 4) "B+NIR" ("Blue+NIR) :(415nm+880nm) : Blue: low: 15mW/cm², medium: 20mW/cm², high: 25mW/cm²; NIR:10mW/cm² **11-001-RBMASK:** 1) "B":(415nm) : low: 15mW/cm² , medium:20mW/cm² , high: 25mW/cm 2) "R+NIR"(630nm+880nm): Red: low: 15mW/cm² , medium: 20mW/cm² , high: 25mW/cm² ; NIR: 10mW/cm² **FCM910:** 1) "RED+NIR"(630nm+880nm): Red:low: 15mW/cm² , medium: 20mW/cm² , high: 25mW/cm² ; NIR: 10mW/cm² 2) "YELLOW+NIR" (590nm+880nm): Yellow: low:5mW/cm² , medium: 7mW/cm² , high: 10mW/cm² ; NIR:10mW/cm² 3) "GREEN":(520nm): low: 3mW/cm², medium: 4mW/cm², high: 5mW/cm² 4) "BLUE" :(415nm) : Blue: low: 15mW/cm² , medium: 20mW/cm² , high: 25mW/cm²	590nm: 15±5mW/cm²; 830nm: 10±5mW/cm²	Red+IR: 30mW/cm² ; Blue: 18mW/cm² ; Amber: 20mW/cm² ; Mixed light: 9mW/cm² ;	Red 17.0 ± 5mW/cm², IR 51.2 ± 5 mW/cm² Total mode = 128 mW/cm² **Skin Clearing [Step 1]:** Blue 64 ± 8 mW/cm², IR 64.0 ± 5 mW/cm² Total mode =128 mW/cm² **Skin Clearing [Step 2]:** Blue 55 ± 6 mW/cm², Red 73 mW/cm² Total mode =128 mW/cm² **Skin Clearing [Step 3]:** Red 73 mW/cm², IR 55 ± 5mW/cm², Total mode =128 mW/cm² **Better Aging:** Red 64 ± 5mW/cm², IR 64 ± 5 mW/cm² Total mode = 128 mW/cm²		15±5mW/cm² 630nm: 20±5mW/cm² 660nm: 25±5mW/cm² 880nm: 10±5mW/cm² 415nm: 25±5mW/cm² Total: 70mW/cm²(wrinkle)-(605nm+630nm+660nm+880nm) 45mW/cm²(acne)-(630nm+415nm)	
Treatment time	**FCM902:** 3 minutes per treatment for "R", "Y+NIR", "G", "B+NIR" mode. 8 minutes per treatment for “Auto mode”. **FCM905, FCM906, FCM908:** 3 minutes for "Red", "Yellow+NIR", "Green", "Blue+NIR" **11-001-RBMASK:** 10 minutes per treatment for "B", "R+NIR" mode.	10 minutes, Wrinkles: 5 x weekly, 6 weeks Acne: 4 x weekly, 6 weeks	For red, blue and red+infrared: 10, 20, 30 minutes	Skin Sustain: 4.3 min (daily after 8 weeks) Skin Clearing: 8.4 min (daily for at least 8 weeks) Better Aging: 6.4 min(daily for at least 8 weeks) Under-eye cooling: may be used with LED treatments or can be used without LEDs active. Variable	10 minutes/day, 3 times per week	3 minutes per treatment	Similar **Note 4**

Item	Subject device K251588	Primary Predicate device 1 K242593	Predicate device 2 K241857	Predicate device 3 K242796	Predicate device 4 K230351	Predicate device 5 K230042	Remark
	FCM910: 3 minutes per treatment for "YELLOW+NIR","RED+NIR" ,"GREEN", "BULE" mode. 8 minutes per treatment for “Auto mode”.			cooling settings are available and may be adjusted by the user. Cooling is intended for refreshing/invigorating/soothing the skin only.			
Dimensions (mm)	**FCM902:** LED Mask: Approximately 2.24 feet x 0.73 feet x 0.08 feet Controller: 0.02 feet x 0.1 feet x 0.35 feet **FCM905, FCM906, FCM908:** LED Mask: Approximately 2.16 feet x 0.73 feet x 0.12 feet Controller: 0.02 feet x 0.1 feet x 0.35 feet **11-001-RBMASK:** LED Mask: Approximately 0.95 feet x 0.73 feet x 0.08 feet Controller: 0.24 feet x 0.24 feet x 0.09 feet **FCM910:** LED Mask: Approximately 1.94 feet x 0.80 feet x 0.32 feet Controller: 0.26 feet x 0.14 feet x 0.08 feet	No publicly available	KFB290: Approximately 302 mm x 197 mm x 22 mm KFB291: Approximately 412 mm x 195 mm x 22 mm	No publicly available	No publicly available	No publicly available	Different **Note 5**
Compliance with voluntary standards	IEC 60601-1:2020 IEC 60601-1-2:2020 IEC 60601-1-11:2020 IEC 60601-2-57:2011 IEC 62471:2006 IEC 62133-2:2017	IEC 60601-1:2005 IEC 60601-1-2:2014 IEC 60601-1-11:2015 IEC 60601-2-57:2023 IEC 62471:2006 IEC 62133-2	IEC 60601-1:2020 IEC 60601-1-2:2020 IEC 60601-1-11:2020 IEC 60601-2-83:2019 IEC 62471:2006 IEC 62133-2:2017	IEC 60601-1:2020 IEC 60601-1-2:2020 IEC 60601-1-11:2020 IEC 60601-2-83:2019 IEC 62471:2006	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; IEC 62133-2	Same
Biocompatibility feature	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same

Comparison in details:

Note 1:

Thought the indication for use of subject device is little different from the predicate devices, the specific description of indication for use can find in predicate devices. Please refer to below table, so this difference should not raise any safety/effectiveness questions.

Note 2:

The power supply for the subject device is different from that of the predicate device, however the lithium battery of the subject device has passed IEC 62133-2 test and the power adapter has been assessed for electrical safety along with the main unit, so this difference should not raise any safety/effectiveness questions.

Note 3:

Although there is little difference of "LED Power" between subject device and predicated devices, both the subject device and predicate device have the same treatment wavelengths (630nm, 880nm, 415nm) and total power density designed in treating the wrinkles and the acne. The subject device has passed the IEC60601-1, IEC60601-1-2, IEC60601-2-57 and IEC62471 test, so the slight difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 4:

The treatment time of these devices are very similar but not identical, treatment is one of the factors to get the intended purpose. What's more, the subject device has passed the IEC60601-1, IEC60601-1-2, IEC60601-2-57 and IEC62471 test, the slight difference will not raise safety and effective issue.

Note 5:

Although the appearance, dimensions are different between the subject and predicate device, these differences are insignificant and do not raise any safety/effectiveness problems.

Conclusion:

LED Light Therapy Mask is substantially equivalent to the predicate devices.

(9) Non-clinical studies and tests performed:

Non-clinical testings have been conducted to verify that the LED Light Therapy 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:

- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11, 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, 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, Photobiological safety of lamps and lamp systems
- IEC 62133-2, 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

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

- ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization
- ISO 10993-23, Biological Evaluation of Medical Devices - Part 23: Tests for Irritation

We have also conducted:

- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"

(10) Conclusion

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