December 19, 2025

Shenzhen Xinlong Precision Plastic Mold Products CO., LTD
% Tracy Che
Registration engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K253054
Trade/Device Name: LED Light Therapy Mask (M19, M19-1, M19-2, M19-3, M19-5, M19-6)
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: September 20, 2025
Received: September 22, 2025

Dear Tracy Che:

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: 2025.12.19 22:42:29 -05'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253054

Please provide the device trade name(s).

LED Light Therapy Mask (M19, M19-1, M19-2, M19-3, M19-5, M19-6)

Please provide your Indications for Use below.

The device is an over the counter device that is intended for:
Red+Infrared light: Treatment of full-face wrinkles;
Red+Blue+Infrared light: Treatment of mild to moderate inflammatory acne;
Yellow+Infrared light: Treatment of full-face wrinkles.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary K253054

"510(k) Summary" as required by 21 CFR Part 807.92.

I. Submitter

Company name: SHENZHEN XINLONG PRECISION PLASTIC MOLD PRODUCTS CO., LTD.
Address: 3rd Floor, Building A, No. 281 Huating Road, Shuiwei Community, Dalang Street, Longhua District, Shenzhen, Guangdong, China

Contact person: Tianfei He

Title: General manager

Tel: +86 13430705129

E-mail: 406904985@qq.com

Date: 2025-12-12

II. Subject Device

Name of Device: LED Light Therapy Mask
Model(s): M19, M19-1, M19-2, M19-3, M19-5, M19-6
Common or Usual Name: Light Based Over The Counter Wrinkle Reduction Over-The-Counter Powered Light Based Laser For Acne
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulatory Class: II
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810

III. Predicate and Reference Devices

➢ Predicate devices

No.	Manufacturer	Device name	Product code	510(k) Number	Cleared Date
1.	Shenzhen Fittop Health Technology Co., Ltd.	LED Light Therapy Mask (FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910)	OHS, OLP, ILY	K251588	2025.08.21
2.	Shenzhen Kaiyan Medical Equipment Co., Ltd	CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (MK-90C, MK-90M,	OHS, OLP	K242593	2025.02.14

No.	Manufacturer	Device name	Product code	510(k) Number	Cleared Date
		MK66RB-F, MK-90N)			
3.	Shenzhen Ulike Smart Electronics Co., Ltd.	Ulike Reglow Light Therapy Device (UM10)	OHS, OLP	K243492	2025.01.10
4.	Guangdong Newdermo Biotech Co.,Ltd	LED light therapy mask (FM-01, FM-02, FM-03)	OHS, OLP, ILY	K223544	2023.02.23

- **Reference device**

No.	Manufacturer	Device name	Product code	510(k) Number	Cleared Date
1.	Shenzhen Nuon Medical Equipment Co., Ltd	Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-72, HD-73A, HD-116, HD-53A, HD-70, HD-59D, HD-72A, HD-73B, HD-116A, HD-53B)	OHS, OLP	K242700	2024.12.19
2.	Shenzhen Siken 3D Technology Development Co., Ltd.	LED Light Therapy Mask (SKB-1818P, SKB-1918,SKB-1918P, SKB-1918PLUS, SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002, SKB-2418)	OHS, OLP	K243040	2024.12.20

IV. Device Description

The LED Light Therapy Mask (Models: M19, M19-1, M19-2, M19-3, M19-5, M19-6) is an Over-the-Counter (OTC), home-use, wearable LED phototherapy device, and intended for the use of treating full-face wrinkles and mild to moderate acne. Light radiates from the inner surface of the device onto the face. This light is generated by LED with four different spectrum wavelengths: red (660nm), infrared (850nm), yellow (590nm) and blue (460nm). The LED Light Therapy Mask is consisting of main unit (mask), controller and USB charging cable.

The device is powered by rechargeable Li-battery and controlled by a controller that is connected to the main unit. The device's power-on/off, mode switch, intensity adjustment and time adjustment can be operated by the controller. The device will automatically shut down when the treatment time is over.

V. Indications for Use

The device is an over the counter device that is intended for:

Red+Infrared light: Treatment of full-face wrinkles;

Red+Blue+Infrared light: Treatment of mild to moderate inflammatory acne;

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

VI. Comparison of Technological Characteristics With the Predicate Device

The LED Light Therapy Mask has the same intended use as the predicates. The technological characteristics, features, specifications, materials are similar to the predicate devices and reference devices. Any minor differences between the subject device and the listed predicate devices and reference devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate devices and reference devices for its intended use.

Therefore, the LED Light Therapy Mask may be found substantially equivalent to its predicate devices and reference devices.

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Reference device 1	Reference device 2	Remark
510(k) Number	Pending	K251588	K242593	K243492	K223544	K242700	K243040	/
Trade name	LED Light Therapy Mask Models M19, M19-1, M19-2, M19-3, M19-5, M19-6	LED Light Therapy Mask (FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910)	CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (MK-90C, MK-90M, MK66RB-F, MK-90N)	Ulike Reglow Light Therapy Device (UM10)	LED light therapy mask (FM-01, FM-02, FM-03)	Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-72, HD-73A, HD-116, HD-53A, HD-70, HD-59D, HD-72A, HD-73B, HD-116A, HD-53B)	LED Light Therapy Mask (SKB-1818P, SKB-1918,SKB-1918P, SKB-1918PLUS, SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002, SKB-2418)	/
Manufacturer	SHENZHEN XINLONG PRECISION PLASTIC MOLD PRODUCTS CO., LTD.	Shenzhen Fittop Health Technology Co., Ltd.	Shenzhen Kaiyan Medical Equipment Co., Ltd	Shenzhen Ulike Smart Electronics Co., Ltd.	Guangdong Newdermo Biotech Co.,Ltd	Shenzhen Nuon Medical Equipment Co., Ltd	Shenzhen Siken 3D Technology Development Co., Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810, 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810	Same
Classification Name	Light Based Over The Counter Wrinkle Reduction, Over-The-Counter Powered Light Based Laser For Acne	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, 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 (OHS), Over-The-Counter Powered Light Based Laser For Acne (OLP), Infrared, Therapeutic Heating (ILY)	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	Same
Product code	OHS, OLP	OHS, OLP, ILY	OHS, OLP	OHS, OLP	OHS, OLP, ILY	OHS, OLP	OHS, OLP	Same
Device classification	Class II	Class II	Class II	Class II	Class II	Class II	Class II	Same
Indication for use/	The device is an over the	The LED Light Therapy Mask	For MK-90C:	Ulike Reglow Light Therapy	Red light: Treatment of	The Radiant Renewal	LED Light Therapy	Same

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Reference device 1	Reference device 2	Remark
510(k) Number	Pending	K251588	K242593	K243492	K223544	K242700	K243040	/
Intended use	counter device that is intended for: Red+Infrared light: Treatment of full-face wrinkles; Red+Blue+Infrared light: Treatment of mild to moderate inflammatory acne; Yellow+Infrared light: Treatment of full-face wrinkles.	(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	The CurrentBody™ LED4 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-90M: The CurrentBody™ LED4 in 1 Zone Facial Mapping Mask (Models:MK-90M) is an over the counter device intended for the use in the treatment of full face wrinkles. For MK66RB-F: The CurrentBody™LED4 in 1 Zone Facial Mapping Mask (Models:MK66RB-F) is an over the counter device, specifically indicated to treat mild to moderate acne vulgaris. For MK-90N: The CurrentBody™ LED4 in 1 Zone Facial Mapping Mask	Device is an over the counter device that is intended for use in the treatment of full face wrinkles and treatment of mild to moderate inflammatory acne	full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Infrared light: 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. Mixed light: Treatment of mild to moderate inflammatory acne.	Skincare Lid (Model: HD-59A, HD-59B, HD-72, HD-73A, HD-116, HD-53A) is intended for the treatment of wrinkles for over-the-counter cosmetic use. The Radiant Renewal Skincare Lid (Model: HD-70) is intended for the treatment of wrinkles and the mild to moderate inflammatory acne for over-the-counter cosmetic use. The Radiant Renewal Skincare Lid (Model: HD-59D, HD-72A, HD-73B,HD-116A,HD-53B) is intended for the treatment of the mild to moderate inflammatory acne for over-the-counter cosmetic use.	Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne	

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Reference device 1	Reference device 2	Remark
510(k) Number	Pending	K251588	K242593	K243492	K223544	K242700	K243040	/
		to moderate inflammatory acne. c. Yellow+Infrared light: Treatment of full-face wrinkles.	(Models:MK-90N) is an over the counter device, is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles.					
Prescription or OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC	Same
Dimension	M19: 311mm×200mm×3.5mm M19-1: 660mm×190mm×3.5mm M19-2: 311mm×191mm×3.5mm M19-3: 191mm×211mm×113mm M19-5: 311mm×191mm×3.5mm M19-6: 311mm×272mm×3.5mm	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	Not publicly available	Not publicly available	FM-01: 207X277X43mm, FM-02: 198X383X33.5mm, FM-03: 237.5X108X8.1mm	Not publicly available	Model SKB-1818P,SKB-1918, SKB-1918P: 194*170*131mm Model SKB-1918PLUS: 217*152*173mm SKB-2318L,SKB-2318P,SKB-2318PRO,IN-FM002,SKB-2418：411*195*4mm	Different

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Reference device 1	Reference device 2	Remark
510(k) Number	Pending	K251588	K242593	K243492	K223544	K242700	K243040	/
		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						
Power supply	Lithium battery 3.7V, 2000mAh	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 MK66RB-F and MK-90M: 3.7Vdc, 2600mAh, 9.62Wh Lithium battery	Controller:3.7V, 2600mAh Lithium battery, 9.62Wh	Input: 100-240 V~, 50/60 Hz, 0.25 A Output: DC 5 V, 500mA	Lithium battery:For models HD-59A, HD-59B, HD-59D, HD-72, HD-72A, HD-73A, HD-73B, HD-116, HD-116A HD-53A, HD-53B: 3.7V, 55mAh, 0.204Wh For model HD-70: 3.7V, 95mAh, 0.3515Wh	Input: AC 100-240V 50-60Hz 0.3A Output: DC 5V 1A 3.7V 650mAh Li-ion Battery 3.7V1000mAh Li-ion Battery	Different
Sterilization	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Same
Light source	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Same
Location for use	Face	Face	Face	Face	Face	Face	Face	Same
Wavelength	Mode 1: 660nm+850nm (red + infrared light) Mode 2: 660nm+460nm+ 850nm (red+blue+infrared	630nm ±5nm visible red light; 880nm±5nm non-visible red light; 415±5nm blue light;	MK-90C Mode1: Red+Infrared (633nm+830nm) Mode 2: Blue+Red	465nm, 590nm, 630nm, 830nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and	HD-59A:Red+IR630±10nm &830±10nm HD-59B:Yellow	SKB-1818P, SKB-1918, SKB- 1918P, SKB-1918PLUS: Blue: 460nm±10nm	Similar

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Reference device 1	Reference device 2	Remark
510(k) Number	Pending	K251588	K242593	K243492	K223544	K242700	K243040	/
	light) Mode 3: 590nm+850nm (yellow + infrared light)	590±5nm yellow light	(415nm+633nm) Mode 3: Yellow+Infrared (590nm+830nm) MK-90M Mode: Red+Infrared (633nm+830nm) MK66RB-F Mode: Red+Blue (633nm +415nm) MK-90N Mode: Yellow+Infrared (590nm+830nm)		850nm and 460nm	590±10nm HD-59D:Blue 415±10nm HD-70:Red+IR light mode630±10nm&830± 10nm Yellow light mode:590±10nm Blue light mode:415±10nm HD-72:Red light mode:630±10nm Yellow light mode:590±10nm HD-72A:Blue 415±10nm HD-73A:Red light mode:630±10nm Yellow light mode:590±10nmHD-73B:Blue 415±10nmHD-116:Red light mode:630±10nmYellow light mode:590±10nmHD-116A:Blue	Red: 620nm±10nm SKB-2318L, SKB-2318P, SKB -2318PRO, IN-FM002, SKB-2 418: Blue: 460nm±10nm Red: 620nm±10nm Infrared: 850nm ± 10nm	

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Reference device 1	Reference device 2	Remark
510(k) Number	Pending	K251588	K242593	K243492	K223544	K242700	K243040	/
						415±10nmHD-53A:Red 630±10nm HD-53B:Blue 415±10nm		
Irradiance	**Mode 1** 13-33mW/cm² **Model 2** 11-31mW/cm² **Mode 3** 5-13mW/cm²	**FCM902, FCM905, FCM906, FCM908:** 1) "R" (Red) (630nm): low: 25mW/cm², 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:	415nm:25±5mW/cm²; 633nm:20±5mW/cm²; 590nm:15±5mW/cm²; 830nm:10±5mW/cm²	1-40mW/cm²	Red light: 2.0~3.0mW/cm² Blue light: 2.0~4.0mW/cm² Infrared light: 2.0~4.0mW/cm² Mixed light: 9.0~12.0mW/cm²	HD59A:Red+IR630 ± 10nm:45~65 830±10nm:30~50 Total:75~115 HD-59B:Yellow590 ± 10nm:10~30 HD-59D:Blue415 ± 10nm:35~50 HD-70:Red+IR light mode:Red 630 ± 10nm:45~65 IR 830±10nm:30~50 Total:75~115 Yellow light mode:590 ±10nm:10~30 Blue light mode:415 ± 10nm:35~50 HD-72Red light mode:630 ± 10nm:15~40 Yellow light mode:590	SKB-1818P: Mode 1: Red: 5.5mW/cm² Mode 2: Blue: 9mW/cm² SKB-1918: Mode 1: Red: 5mW/cm² Mode 2: Blue: 6mW/cm² SKB-1918P: Mode 1: Red: 6mW/cm² Mode 2: Blue: 6.5mW/cm² SKB-1918PLUS: Mode 1: Red: 3.5mW/cm² Mode 2: Blue: 4.0mW/cm² SKB-2318L,SKB-2318P, SKB-	Similar

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Reference device 1	Reference device 2	Remark
510(k) Number	Pending	K251588	K242593	K243492	K223544	K242700	K243040	/
		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				±10nm: 8~30 HD-72A:Blue 415 ± 10nm:35~50 HD-73ARed light mode:630 ± 10nm:15~40 Yellow light mode:590 ±10nm:8~30 HD-73B:Blue 415 ± 10nm:35~50 HD-116Red light mode:630 ± 10nm:15~40 Yellow light mode:590 ±10nm:8~30 HD-116A:Blue 415 ± 10nm:35~50 HD-53A:Red 630 ± 10nm:20~40 HD-53B:Blue 415 ± 10nm:35~50	2318PRO, IN-FM002,SKB-2418: Mode 1: Red：3.5～10mW/cm² Mode 2: Blue：2.5～8mW/cm² Mode 3: Red+Infrared Light：6～27mW/cm²	

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Reference device 1	Reference device 2	Remark
510(k) Number	Pending	K251588	K242593	K243492	K223544	K242700	K243040	/
Treatment time	5/10/20min	**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. **FCM910:** 3 minutes per treatment for "YELLOW+ NIR", "RED+NIR" ,"GREEN", "BULE" mode.	10min	Not publicly available	Manual Mode: 15minutes each time, Automatic Mode: 10minutes each time. 3-4 treatment a week, reduce to 1-2 treatment a week once the results shown.	2min	It is recommended to use it for 10 minutes a day, 3 times per week.	Similar

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Reference device 1	Reference device 2	Remark
510(k) Number	Pending	K251588	K242593	K243492	K223544	K242700	K243040	/
		8 minutes per treatment for "Auto mode".						
Compliance with voluntary standards	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-83 IEC 62133-2 IEC 62471	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 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-57 IEC 62133-2 IEC 62471	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-57 IEC 60601-2-83 IEC 62133-2 IEC 62471	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11: 2020 IEC 60601-2-57: 2011	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 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	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	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same

VII.Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the LED Light Therapy Mask was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 4, 2020", as recommended by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5 Third edition 2009-06-01, Biological Evaluation of Medical Devices - Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

2) Electrical Safety

Electrical safety and EMC testing were performed to, and passed, as per the following standards:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: electromagnetic compatibility
- IEC TS 60601-4-2 Edition 1.0 2024-03 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, Medical Electrical Equipment - Part 1: 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+A1: 2022, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62133-2 Edition 1.1 2021-07 CONSOLIDATED VERSION 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

3) Eye safety

- IEC 62471 First edition 2006-07, Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with ***Basic Documentation Level*** of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

VIII. Conclusions

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