August 31, 2026

Kam Yuen Plastic Products , Ltd.
% Jett Lee
Regulation Manager
Guangdong Jianda Medical Technology Co., Ltd.
6f, #1 Tiantai Rd., Science City, Luogang District
Guangzhou, / 510663
China

Re: K260767
Trade/Device Name: Facial Beauty Device (Facial Mask LED Beauty Device A-901; Facial LED & EMS Beauty Device A-902; Facial Mask LED & EMS Beauty Device A-907)
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, NFO, IRO
Dated: August 3, 2026
Received: August 3, 2026

Dear Jett Lee:

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: 2026.08.31 21:31:30 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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.

Submission Number *(if known)*

K260767

Device Name

Facial Beauty Device (Facial Mask LED Beauty Device A-901; Facial LED & EMS Beauty Device A-902; Facial Mask LED & EMS Beauty Device A-907)

Indications for Use *(Describe)*

Facial Mask LED Beauty Device A-901 is an over-the-counter device. The Red light mode is intended for the treatment of full face wrinkles. The Red and Infrared light combination mode is intended for the treatment of full-face wrinkles. The blue light mode is intended for the treatment of mild to moderate inflammatory acne. The device is indicated for adults only.
Facial LED & EMS Beauty Device A-902 is an over-the-counter device. The Red light mode is intended for the treatment of facial wrinkles. The EMS mode is intended for facial stimulation. The Blue light mode is intended for the treatment of mild to moderate inflammatory acne. The device is indicated for adults only.
Facial Mask LED & EMS Beauty Device A-907 is an over-the-counter device. The Red light mode is intended for the treatment of periorbital wrinkles. The EMS mode is intended for facial stimulation. The Blue light mode is intended for the treatment of mild to moderate inflammatory acne. The device is indicated for adults only.
The devices are intended for use on Fitzpatrick skin types I, II, and III.

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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Date of the summary prepared: August 25, 2026

510(k) Summary of K260767

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1 Submitter Information

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Company: Guangdong Jianda Medical Technology Co., Ltd

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Phone: 86-13512755282

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2 Subject Device Information

Type of 510(k) submission: Traditional

Common or Usual Name: Light Based Over the Counter Wrinkle Reduction / Over-the-Counter Powered Light Based Laser for Acne / Stimulator, Transcutaneous Electrical, Aesthetic Purposes / Vibratior, Therapeutic

Trade Name: Facial Beauty Device

Model: Facial Mask LED Beauty Device A-901, Facial LED & EMS Beauty Device A-902, Facial Mask LED & EMS Beauty Device A-907

Review Panel: General & Plastic Surgery / Neurology

Product Code: OHS, OLP, NFO, IRO

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology / Transcutaneous Electrical Nerve Stimulator For Pain Relief / Therapeutic vibrator

Regulation Number: 21 CFR 878.4810 / 882.5890 / 890.5975

Regulation Class: 2

3 Predicate Device Information

For Facial Mask LED Beauty Device A-901

Device Name and model	TheraFace Mask	LED Facial Mask MZ-01, NEWKEY-01, SP- FM-01
510K No.	K230293	K230351
Regulation No.	878.4810	878.4810
Regulation class	Class 2	Class 2
Product code	OHS, OLP	OHS, OLP

For Facial LED & EMS Beauty Device A-902

Device Name and model	LED Facial Mask MZ-01, NEWKEY-01, SP-FM-01	Luna™ 4 plus	Micro-current Facial Beauty Device AM-810W, AM-810B, AM-812W, AM-812B	SonicLift Model: ST261 (Reference device)
510K No.	K230351	K241102	K243430	K150077
Regulation No.	878.4810	878.4810, 882.5890	882.5890	882.5890 890.5975
Regulation class	Class 2	Class 2	Class 2	Class 2
Product code	OHS, OLP	OHS, NFO	NFO	NFO, IRO

For Facial Mask LED & EMS Beauty Device A-907

Device Name and model	LED Facial Mask MZ-01, NEWKEY-01, SP-	Luna™ 4 plus	Micro-current Facial Beauty Device

	FM-01		AM-810W, AM-810B, AM-812W, AM-812B
510K No.	K230351	K241102	K243430
Regulation No.	878.4810	878.4810, 882.5890	882.5890
Regulation class	Class 2	Class 2	Class 2
Product code	OHS, OLP	OHS, NFO	NFO

4 Device Description

Facial Beauty Device includes three models—Facial Mask LED Beauty Device A-901, Facial LED & EMS Beauty Device A-902, and Facial Mask LED & EMS Beauty Device A-907. These devices are intended to improve the appearance of full-face wrinkles, periorbital wrinkles, facial wrinkles, and mild to moderate inflammatory acne using LED light therapy and EMS (Electrical Muscle Stimulation) technology. The devices are intended for use on Fitzpatrick skin types I, II, and III.

1) Facial Mask LED Beauty Device A-901

Facial Mask LED Beauty Device A-901 consists of a full-face shape mask, a controller with battery and an AC power adapter, which directly applies light onto the face skin surface and makes use of specific light spectral characteristics. The device has LEDs distributed on the mask and it can operated in three operation modes: Blue light, Red light and Red combined with Near infrared light, which can emit Blue (415±10 nm) light, Red (630±10 nm) light or Red + NIR (near infrared, 830±10 nm) light. The Red light is intended for the treatment of full face wrinkles. The Red and NIR light is intended for the treatment of full-face wrinkles. The Blue light is intended for the treatment of the mild to moderate inflammatory acne. Each mode can shutdown in 10 minutes automatically.

2) Facial LED & EMS Beauty Device A-902

Facial LED & EMS Beauty Device A-902 consists of a V-shaped mask with elastic belt, an infrared remote with battery, and an AC power adapter, which directly applies light and microcurrent electrical stimulation current onto the facial skin surface and makes use of specific light spectral characteristics or microcurrent electrical stimulation current. By

adjusting the position of the mask and belt, the device can be applied to different positions of the face. The device designed with four operation modes: Red light, Blue light, Microcurrent electrical stimulation and Vibration mode. It has LEDs distributed on the mask which can emit Blue (460±10 nm) light, Red (620±10 nm) light. In the Microcurrent electrical stimulation mode, the device can output microcurrent electrical stimulation current to the facial skin via the electrodes in the mask. The Red light mode is intended for the treatment of facial wrinkles. The Microcurrent electrical stimulation mode is intended for facial stimulation. The Blue light mode is intended for the treatment of mild to moderate inflammatory acne. The Vibration mode is intended to provide soothing relaxation with continuous gentle vibrations. Each mode can shutdown in 10 minutes automatically.

The Vibration function has no medical purpose and operates independently which does not alter the device's intended medical use.

3) Facial Mask LED & EMS Beauty Device A-907

Facial Mask LED & EMS Beauty Device A-907 consists of a half face shape mask, an infrared remote with battery, a mask holder and an AC power adapter, which directly applies light and microcurrent electrical stimulation current onto the face skin surface and makes use of specific light spectral characteristics or microcurrent electrical stimulation current. The device designed with three operation modes: Red light, Blue light and Microcurrent electrical stimulation mode. It has LEDs distributed on the mask which can emit Blue (460±10 nm) light, Red (620±10 nm) light. In the Microcurrent electrical stimulation mode, the device can output microcurrent electrical stimulation current to the facial skin via the electrodes in the mask. The Red light mode is intended for the treatment of periorbital wrinkles. The Microcurrent electrical stimulation mode is intended for facial stimulation. The Blue light mode is intended for the treatment of mild to moderate inflammatory acne. Each mode can shutdown in 10 minutes automatically.

Remote controller:

For the remote of A-902 and A-907, the device operation can be controlled by controller via infrared light. It does not include any patient data. Infrared remote controls use infrared (IR) light to convey information. The infrared light is emitted from an IR LED controlled by the modulated signal from the transmitter's MCU. Modulation can help the receiver distinguish

the desired signals from other infrared noise sources. And the remote controlling operation distance is very short. So, no any cybersecurity issue may caused by such the remote controlling communication.

Eye Safety and Required Protective Eyewear

This device emits optical radiation that may pose a hazard to the user's eyes during operation. The device is not supplied with protective eyewear. Users must provide their own professional protective eyewear that meets the following minimum optical specifications prior to operating the device:

- Wavelength coverage: 400 nm – 850 nm
- Optical density (OD): ≥ 6.0

5 Intended Use / Indications for Use

1) Facial Mask LED Beauty Device A-901

Facial Mask LED Beauty Device A-901 is an over-the-counter device. The Red light mode is intended for the treatment of full face wrinkles. The Red and Infrared light combination mode is intended for the treatment of full-face wrinkles. The blue light mode is intended for the treatment of mild to moderate inflammatory acne. The device is indicated for adults only.

2) Facial LED & EMS Beauty Device A-902

Facial LED & EMS Beauty Device A-902 is an over-the-counter device. The Red light mode is intended for the treatment of facial wrinkles. The Microcurrent electrical stimulation mode is intended for facial stimulation. The Blue light mode is intended for the treatment of mild to moderate inflammatory acne. The device is indicated for adults only.

3) Facial Mask LED & EMS Beauty Device A-907

Facial Mask LED & EMS Beauty Device A-907 is an over-the-counter device. The Red light mode is intended for the treatment of periorbital wrinkles. The Microcurrent electrical stimulation mode is intended for facial stimulation. The Blue light mode is intended for the treatment of mild to moderate inflammatory acne. The device is indicated for adults only.

The devices are intended for use on Fitzpatrick skin types I, II, and III.

6 Comparison to predicate device and conclusion

6.1 SE comparison of Facial Mask LED Beauty Device A-901

Features	**Subject Device**	**Predicate Device K230293**	**Predicate Device K230351**
Regulation Information			
Device Name and Model	Facial Beauty Device Facial Mask LED Beauty Device A-901	TheraFace Mask	LED Facial Mask MZ-01, NEWKEY-01, SP- FM-01
510(k) Number	Applying	*K230293*	K230351
Regulation number	878.4810	*878.4810*	878.4810
Classification	Class 2	*Class 2*	Class 2
Product code	OHS, OLP	*OHS, OLP*	OHS, OLP
Intended Use	Facial Mask LED Beauty Device A-901 is an over-the-counter device. The Red light mode is intended for the treatment of full face wrinkles. The Red and Infrared light combination mode is intended for the treatment of full-face wrinkles. The blue light mode is intended for the treatment of mild to moderate inflammatory acne. The device is indicated for adults only.	●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	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.
Indications for Use	OTC	OTC	OTC

Performance Comparison			
Location for use	Face	Face	Face
Treatment time	10 minutes / day, 3-4 days per week	LED: 3 minutes each light mode for a total of 9 minutes per treatment, recommended to use 2 to 5 times per week.	10 minutes/day, 3 times per week
Power supply	External battery charger Input: 100-240V AC, 50/60 Hz Output: 5.0V DC powered by Li-Ion Batteries (3.7V 1500mAh)	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	An external adapter Input: AC 100-240V, 50-60Hz 0.2A Output: DC 12V 0.5A
Software control	YES	YES	Unknown
Irradiance source	LED Light emitting diodes (LEDs)	Light emitting diodes (LEDs)	Light emitting diodes (LEDs)
Wavelength	Blue light: 460±10 nm Red light: 620±10 nm NIR(Infrared) light: 850±10 nm	Red: 633±10nm Blue: 415±10nm Red+IR:633nm±10nm/830±10 nm	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm
Irradiance (mW/cm^2)	Blue: 60.7mW/cm^2 Red: 66.5mW/cm^2 Red+IR: 66.5mW/cm^2 / 52.5mW/cm^2	Red: 73±5mW/cm^2 Blue: 64±5mW/cm^2 Red+IR: 73±5mW/cm^2 / 55±5mW/cm^2	Blue: 15~63mW/cm^2 Red: 31~75mW/cm^2
Main Materials	ABS, Silicone	ABS and PC plastic	ABS and PC plastic
Safety Comparison			

Electrical Safety	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	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC 62471
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	Comply with ISO10993-1, ISO10993-5 and ISO10993-10

The technological characteristics, features, specifications, materials, and intended use of Facial Beauty Device (Facial Mask LED Beauty Device A-901) is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

6.2 SE comparison of Facial LED & EMS Beauty Device A-902

Features	**Subject Device**	**Predicate Device** **K241102**	**Predicate Device** **K243430**	**Predicate Device** **K230351**	**Reference Device** **K150077**
Regulation Information					
Device Name and Model	Facial Beauty Device Facial LED & EMS Beauty Device A-	Luna™ 4 plus	Micro-current Facial Beauty Device AM-810W, AM-810B, AM-812W, AM-812B	LED Facial Mask MZ-01, NEWKEY-01, SP-FM-01	SonicLift Model: ST261

	902				
510(k) Number	Applying	K241102	K243430	K230351	K150077
Regulation number	878.4810 882.5890 890.5975	878.4810 882.5890	882.5890	878.4810	882.5890 890.5975
Classification	Class 2	Class 2	Class 2	Class 2	Class 2
Product code	OHS, OLP, NFO, IRO	OHS, NFO	NFO	OHS, OLP	NFO, IRO
Intended Use	Facial LED & EMS Beauty Device A-902 is an over-the-counter device. The Red light mode is intended for the treatment of facial wrinkles. The Microcurrent	Luna 4 plus is a Near-Infrared Heated Cleansing Device With Red LED/NIR light & Microcurrent Massage. Microcurrent: indicated for facial	Micro-current Facial Beauty Device is a handheld portable device for over the counter aesthetic use including facial and neck stimulation.	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.	This device is intended for facial stimulation and is indicated for over-the-counter cosmetic use.

	electrical stimulation mode is intended for facial stimulation. The Blue light mode is intended for the treatment of mild to moderate inflammatory acne. The device is indicated for adults only.	stimulation RED+NIR: indicated to treat periorbital wrinkles			
Indications for Use	OTC	OTC	OTC	OTC	OTC
Device Characteristics					
Location for use	Face	Face	Face and neck	Face	Face
Treatment time	10 minutes / day, 3-4 days per week	Yes (1-4 min) (adjustable)	MS-Micro current stimulation mode: It is recommended to use the product 10-15 minutes at a	10 minutes/day, 3 times per week	Unknown

			time / 2-3 times a week.		
Power supply	External battery charger Input: 100-240V AC, 50/60 Hz Output: 5.0V DC powered by Li-Ion Batteries (3.7V 600mAh)	Internal rechargeable Lithium battery	Adapter input: 5V 0.5A Internal battery: 3.7V/600mAh Rechargeable lithium battery	An external adapter Input: AC 100-240V, 50-60Hz 0.2A Output: DC 12V 0.5A	3.7V Li-battery
Software/Firmware Control	YES	Yes	Yes	Unknown	Yes
Automatic Overload Trip	Yes	Not required due to circuit design	Unknown	Unknown	No
Automatic Shut off	Yes	Yes	Unknown	Unknown	No
For Micro current facial stimulation function					
Waveform shape	Pulsed, symmetric biphasic, rectangular	Modulated square	Biphasic pulsed square wave	N/A	Pulsed Biphasic Rectangular

Maximum Output Voltage	285mV @500Ω 935mV @2kΩ 3.85V@10kΩ	0.28V @500Ω 1.11V @2KΩ 5.50V @10KΩ	225mV @ 500Ω 900mV @ 2kΩ 3.60V @ 10kΩ	N/A	156mV @ 500Ω 780mV @ 2kΩ 2.60V @ 10kΩ
Maximum Output Current	570μA @500Ω 467μA @2kΩ 385μA @10kΩ	560μA @500Ω 555μA @2KΩ 552μA @10KΩ	450μA @500Ω 450μA @2KΩ 360μA @10KΩ	N/A	310μA @500Ω 390μA @2KΩ 260μA @10KΩ
Pulse width range	4.2 ms	290 μs	4ms	N/A	112ms
Frequency Range	60Hz	46Hz	57Hz	N/A	8.93Hz
Net Charge	0 μC @ 500Ω	0 μC(charge - balanced)	0 μC @ 500Ω	N/A	0 mC @ 500Ω
Maximum Current Density (Electrode Size: 2.5cm²)	0.164 mA/cm² @500 Ω	1.37 mA/cm² @500 Ω	AM-810B, AM-810W: 0.10mA/cm2@500Ω AM-812B, AM-812W: 0.06mA/cm2@500Ω	N/A	0.0194 mA/cm² @500 Ω
Maximum Power Density (Electrode Size: 2.5cm²)	0.034 mW/cm² @500 Ω	0.38 mW/cm² @500 Ω	AM-810B, AM-810W: 0.0117mW/cm2@500Ω AM-812B, AM-812W: 0.0072mW/cm2@500Ω	N/A	0.003 mW/cm² @500 Ω
Total Energy per Treatment Session	50.4 mJ	37.6 mJ	91.1 mJ	/	/

For LED red light irradiation function					
Irradiance source	LED Light emitting diodes (LEDs)	LED Light emitting diodes (LEDs)	LED Light emitting diodes (LEDs)	Light emitting diodes (LEDs)	/
Wavelength	Blue light: 460±10 nm Red light: 620±10 nm	RED light:633nm±10nm Red+IR: 633±10nm / 850nm±10nm	Blue light: 415±10 nm Red light: 630±10 nm	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm	/
Irradiance (mW/cm^2)	Blue: 60.7mW/cm^2 Red: 66.5mW/cm^2	RED+IR:63 mW/cm^2	Blue: 50mW/cm^2 Red: 80mW/cm^2	Blue: 15~63mW/cm^2 Red: 31~75mW/cm^2	/
Additional Features					
Weight	200g	150g	AM-810B, AM-810W: 118g AM-812B, AM-812W: 130g	Unknown	Main unit: 248g Charge station: 200g Charger Adapter: 180g
Dimensions (mm)	188*52*260	82*38*102	AM-810B, AM-810W: 135*85*39mm AM-812B, AM-812W: 110*92*68mm	Unknown	3.7" L x 7.6" W x 2.8" D
Main Materials	ABS /PC plastic,	Body-safe silicone,	ABS, PC	Unknown	ABS plastic

	Silicone, Stainless steel	ABS plastic, copper, glass, gold, zinc alloy			
User interface	Power button ON/OFF Remote Control: LCD Screen Intensity +/- button Mode Switch button	Power button on/Off Deep cleansing mode button Regular cleansing mode button	Unknown	Unknown	Unknown
Environment for operating	Temperature: +10°C~+35°C Relative humidity: 3%~75% RH Pressure: 70 Kpa~106 KPa	Temperature: 5 ~ 40°C Relative humidity:40% ~ 80%	Unknown	Unknown	Temperature: 5 ~ 40°C Humidity: 80% RH
Environment for storage	Temperature: -40°C~+70°C Relative humidity: 10%~95% RH Pressure: 50 Kpa~106 KPa	Temperature: -10 ~ 50° C Relative humidity: 30%~ 80%	Unknown	Unknown	Temperature: 5 ~ 40°C Humidity: 80% RH
Safety Information					
Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC60601-1-2	IEC 60601-1

	IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10 IEC 60601-2-57 IEC 62471	IEC 60601-1-2 IEC 60601-2-10 IEC 62471	IEC 60601-1-2 IEC 60601-2-10 IEC 62471	IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC 62471	IEC 60601-1-2 IEC 60601-2-10
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	Comply with ISO10993-1, ISO10993-5 and ISO10993-10	ISO 10993-5 ISO 10993-10

The technological characteristics, features, specifications, materials, and intended use of Facial Beauty Device (Facial LED & EMS Beauty Device A-902) is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

As the subject device (A-902) has a vibration function for facial relaxation, which is substantially equivalent to SonicLift, Model: ST261 (K150077). The classification product code of the subject device is OHS/OLP/NFO while the subsequent product code for the vibration function is IRO (510(k)-exempt). Therefore, K241102 / K243430 / K230351 are regarded as the main predicate devices, and K150077 is selected to be the reference device for the vibration function.

Features	**Subject Device**	**Predicate Device** **K241102**	**Predicate Device** **K243430**	**Predicate Device** **K230351**
Regulation Information				

Device Name and Model	Facial Beauty Device Facial Mask LED & EMS Beauty Device A-907	Luna™ 4 plus	Micro-current Facial Beauty Device AM-810W, AM-810B, AM-812W, AM-812B	LED Facial Mask MZ-01, NEWKEY-01, SP- FM-01
510(k) Number	Applying	K241102	K243430	K230351
Regulation number	878.4810 882.5890	878.4810, 882.5890	882.5890	878.4810
Classification	Class 2	Class 2	Class 2	Class 2
Product code	OHS, OLP, NFO	OHS, NFO	NFO	OHS, OLP
Intended Use	Facial Mask LED & EMS Beauty Device A-907 is an over-the-counter device. The Red light mode is intended for the treatment of periorbital wrinkles. The Microcurrent electrical stimulation mode is intended for facial stimulation. The Blue light mode is	Luna 4 plus is a Near-Infrared Heated Cleansing Device With Red LED/NIR light & Microcurrent Massage. Microcurrent: indicated for facial stimulation RED+NIR: indicated to treat periorbital wrinkles	Micro-current Facial Beauty Device is a handheld portable device for over the counter aesthetic use including facial and neck stimulation.	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.

	intended for the treatment of mild to moderate inflammatory acne. The device is indicated for adults only.			
Indications for Use	OTC	OTC	OTC	OTC
Device Characteristics				
Location for use	Periorbital	Face	Face and neck	Face
Treatment time	10 minutes / day, 3-4 days per week	Yes (1-4 min) (adjustable)	MS-Micro current stimulation mode: It is recommended to use the product 10-15 minutes at a time / 2-3 times a week.	10 minutes/day, 3 times per week
Power supply	External battery charger Input: 100-240V AC, 50/60 Hz Output: 5.0V DC powered by Li-Ion Batteries (3.7V 1000mAh)	Internal rechargeable Lithium battery	Adapter input: 5V 0.5A Internal battery: 3.7V/600mAh Rechargeable lithium battery	An external adapter Input: AC 100-240V, 50-60Hz 0.2A Output: DC 12V 0.5A
Software/Firmware Control	YES	Yes	Yes	Unknown

Automatic Overload Trip	Yes	Not required due to circuit design	Unknown	Unknown
Automatic Shut off	Yes	Yes	Unknown	Unknown
For Micro current facial stimulation function				
Waveform shape	Pulsed, symmetric biphasic, rectangular	Modulated square	Biphasic pulsed square wave	N/A
Maximum Output Voltage	280mV @500Ω 900mV @2kΩ 3.60V@10kΩ	0.28V @500Ω 1.11V @2KΩ 5.50V @10KΩ	225mV @ 500Ω 900mV @ 2kΩ 3.60V @ 10kΩ	N/A
Maximum Output Current	560μA @500Ω 450μA @2kΩ 360μA @10kΩ	560μA @500Ω 555μA @2KΩ 552μA @10KΩ	450μA @500Ω 450μA @2KΩ 360μA @10KΩ	N/A
Pulse width range	4.2 ms	290 μs	4ms	N/A
Frequency Range	60.Hz	46Hz	57Hz	N/A
Net Charge	0 μC @ 500Ω	0 μC(charge -balanced)	0 μC @ 500Ω	N/A
Maximum Current Density (Electrode Size: 6cm²)	0.067 mA/cm² @500 Ω	1.37 mA/cm² @500 Ω	AM-810B, AM-810W: 0.10mA/cm2@500Ω AM-812B, AM-812W: 0.06mA/cm2@500Ω	N/A

Maximum Power Density (Electrode Size: 6cm²)	0.013 mW/cm² @500 Ω	0.38 mW/cm² @500 Ω	AM-810B, AM-810W: 0.0117mW/cm2@500Ω AM-812B, AM-812W: 0.0072mW/cm2@500Ω	N/A
Total Energy per Treatment Session	48.0 mJ	37.6 mJ	91.1 mJ	/
For LED red light irradiation function				
Irradiance source	LED Light emitting diodes (LEDs)	LED Light emitting diodes (LEDs)	LED Light emitting diodes (LEDs)	Light emitting diodes (LEDs)
Wavelength	Blue light: 460±10 nm Red light: 620±10 nm	RED light:633nm±10nm Red+IR: 633±10nm / 850nm ±10nm	Blue light: 415±10 nm Red light: 630±10 nm	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm
Irradiance (mW/cm^2)	Blue: 60.7mW/cm^2 Red: 66.5mW/cm^2	RED+IR:63 mW/cm²	Blue: 50mW/cm^2 Red: 80mW/cm^2	Blue: 15~63mW/cm^2 Red: 31~75mW/cm^2
Additional Features				
Weight	325g	150g	AM-810B, AM-810W: 118g AM-812B, AM-812W: 130g	Unknown
Dimensions (mm)	182*97.5*140	82*38*102	AM-810B, AM-810W: 135*85*39mm	Unknown

			AM-812B, AM-812W: 110*92*68mm	
Main Materials	ABS /PC plastic, Silicone, Stainless steel	Body-safe silicone, ABS plastic, copper, glass, gold, zinc alloy	ABS, PC	Unknown
User interface	Power button ON/OFF Remote Control: LCD Screen Intensity +/- button Mode Switch button	Power button on/Off Deep cleansing mode button Regular cleansing mode button	Unknown	Unknown
Environment for operating	Temperature: +10°C~+35°C Relative humidity: 3%~75% RH Pressure: 70 Kpa~106 KPa	Temperature: 5 ~ 40°C Relative humidity:40% ~ 80%	Unknown	Unknown
Environment for storage	Temperature: -40°C~+70°C Relative humidity: 10%~95% RH Pressure: 50 Kpa~106 KPa	Temperature: -10 ~ 50° C Relative humidity: 30%~ 80%	Unknown	Unknown
Safety Information				
Electrical Safety	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC60601-1-2 IEC60601-1

	IEC 60601-1-11 IEC 60601-2-10 IEC 60601-2-57 IEC 62471	IEC 60601-2-10 IEC 62471	IEC 60601-2-10 IEC 62471	IEC60601-1-11 IEC60601-2-57 IEC 62471
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	Comply with ISO10993-1, ISO10993-5 and ISO10993-10

The technological characteristics, features, specifications, materials, and intended use of Facial Beauty Device (Facial Mask LED & EMS Beauty Device A-907) is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Substantially Equivalent (SE) Conclusion:

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices K241102, K243430 and K230351.

7 Summary for non-clinical test

The non-clinical testing was provided to demonstrate the subject device met the acceptance criteria of the test methodology or standards listed below.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the Facial Beauty Device 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: 2009, Biological evaluation of medical devices –Par t 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation

2) Electrical Safety

- IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11:2020 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 60601-2-10:2012+A1:2016+A2:2023 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-2-57: 2023 for use in conjunction with IEC 60601-1:2005, Medical electrical equipment -- Part 2: 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 62471:2006 Photobiological safety of lamps and lamp systems

3) 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.

8 Summary for clinical test

Not applicable

9 Conclusion

The subject device Facial Beauty Device has all features of the predicate devices for intended use. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate devices.