



December 5, 2025

Shenzhen Siken 3D Technology Development Co., Ltd.  
% Bing Huang  
Registration Specialist  
Feiying Drug & Medical Consulting Technical Service Group  
Rm 2401 Zhenye International Business Center, No. 3101-90  
Qianhai Road  
Shenzhen, Guangdong 518052  
China

Re: K252142

Trade/Device Name: Multi-functional Facial Beauty Device (SKB-1703,SKB-1803,SKB-1809, SKB-1909, SKB-2109,SKB-2129,SKB-2208PRO, SKB-2209)

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: November 12, 2025

Received: November 12, 2025

Dear Bing Huang:

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](mailto: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: 2025.12.05  
14:34:31 -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

510(k) Number (if known)  
K252142

Device Name

Multi-functional Facial Beauty Device (SKB-1703, SKB-1803, SKB-1809, SKB-1909, SKB-2109, SKB-2129, SKB-2208PRO, SKB-2209)

Indications for Use (Describe)

Multi-functional Facial Beauty Device (model: SKB-1909):

- Blue light is intended for the treatment of facial mild to moderate inflammatory acne.
- Red light is intended for the treatment of facial wrinkles.

Multi-functional Facial Beauty Device (model: SKB-1703):

- Blue light is intended for the treatment of facial mild to moderate inflammatory acne.

Multi-functional Facial Beauty Device (models SKB-1803, SKB-1809, SBK-2109, SKB-2129, SKB-2208PRO and SKB-2209):

- Red light is intended for the treatment of facial 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.

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# 510(k) Summary #K252142

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

**Date: 2025-11-24**

## I. Submitter

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## II. Device

Name of Device: Multi-functional Facial Beauty Device (SKB-1703, SKB-1803, SKB-1809, SKB-1909, SKB-2109, SKB-2129, SKB-2208PRO, SKB-2209)  
Common or Usual Name: Light Based Over The Counter Wrinkle Reduction  
Over-The-Counter Powered Light Based For Acne  
Classification 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 Device & Reference Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
Galactic Beauty, LLC	MMSphere™	K190443	June 24, 2019
Shenzhen Aozemei Technology Co., LTD	Micro-current Facial Beauty Device (Model(s): AM-810W, AM-810B, AM-812W, AM-812B)	K241718	October 28, 2024

Reference device:

Manufacturer	Reference Device	510(k) Number	Cleared Date
Li-Tek Electronics Technology Co., Ltd.	Micro-current facial cold and hot service (model: TPML-100)	K213039	May 25, 2022

#### **IV. Device Description**

The Multi-functional Facial Beauty Device is a portable, non-sterile, reusable device designed to achieve the aesthetic effect. It consists of main unit, charging cable and user manual. The device is supplied by internal rechargeable lithium battery, which can be recharged by external charger through the Type-C charging cable. The device is un-usable when charging.

The device is only home environment use, which has some massage heads, and LED light mode (Red and /or Blue lights are output independently) to provides following functions.

- a. Micro-current stimulation function.
- b. Red LED irradiation function.
- c. Blue LED irradiation.
- d. Hot compress and vibration function. (The vibration is classified as class I and not need for 510K, and the hot compress ( $39^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ ) is not for medical purpose).
- e. Hot compress function. (The hot compress ( $35.5^{\circ}\text{C} \sim 38.5 \pm 0.5^{\circ}\text{C}$ ) is not for medical purpose).
- f. Vibration function. (The vibration is classified as class I and not need for 510K).

Each mode of the Multi-functional Facial Beauty Device is independent from all other modes of the device.

#### **V. Indications for Use**

Multi-functional Facial Beauty Device (model: SKB-1909):

- Blue light is intended for the treatment of facial mild to moderate inflammatory acne.
- Red light is intended for the treatment of facial wrinkles.

Multi-functional Facial Beauty Device (model: SKB-1703):

- Blue light is intended for the treatment of facial mild to moderate inflammatory acne.

Multi-functional Facial Beauty Device (models SKB-1803, SKB-1809, SBK-2109, SKB-2129, SKB-2208PRO and SKB-2209):

- Red light is intended for the treatment of facial wrinkles.

#### **VI. Comparison of Technological Characteristics With the Predicate Device**

Multi-functional Facial Beauty Device is compared with the following Predicate Devices and Reference device in terms of intended use, design, specifications, and performance:

<b><u>Comparison Elements</u></b>	<b><u>Subject Device</u></b>	<b><u>Predicate Device 1</u></b>	<b><u>Predicate Device 2</u></b>	<b><u>Reference device</u></b>	<b><u>Remark</u></b>
510(k) Number	K252142	K190443	K241718	K213039	/
Trade name	Multi-functional Facial Beauty Device  (Model(s):SKB-1703,SKB-1803,SKB-1809, SKB-1909,SKB-2109,SKB-2129,SKB-2208PRO, SKB-2209)	MMSphere™	Micro-current Facial Beauty Device (Model(s): AM-810W, AM-810B, AM-812W, AM-812B)	Micro-current vibration facial cold and hot service (model: TPML-100)	/
Manufacturer	Shenzhen Siken 3D Technology Development Co., Ltd	Galactic Beauty, LLC	Shenzhen Aozemei Technology Co., LTD	Li-Tek Electronics Technology Co., Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	<u>Same</u>
Product code	OHS, OLP	OHS, OLP	OHS, OLP	OHS, OLP	<u>Same</u>
Device classification	II	II	II	II	<u>Same</u>
Prescription or OTC	OTC	OTC	OTC	OTC	<u>Same</u>
Indication for use/ Intended use	Multi-functional Facial Beauty Device (model: SKB-1909): - Blue light is intended for the treatment of	MMSphere™ Light Therapy Device emits energy in the red, blue and amber regions of the spectrum, specifically indicated to treat wrinkles and/or mild to moderate acne. The	Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne.	<u>Micro-current vibration facial cold and hot service is an over the counter device that is indicated for the treatment of mild to moderate inflammatory acne and facial stimulation</u>	<u>Same</u>

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference device</u>	<u>Remark</u>
	facial mild to moderate inflammatory acne. - Red light is intended for the treatment of facial wrinkles. Multi-functional Facial Beauty Device (model: SKB-1703): - Blue light is intended for the treatment of facial mild to moderate inflammatory acne. Multi-functional Facial Beauty Device (models SKB-1803, SKB-1809, SBK-2109, SKB-2129, SKB-2208PRO and SKB-2209): - Red light is intended for the treatment of facial wrinkles.	MMSphere™ is designed to be used for 20 minute treatments three to seven times per week.		<u>for over the counter aesthetic use.</u>	
Handheld or stationary	Hand-held Type	Both	Hand-held Type	Hand-held Type	<u>Same</u>

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference device</u>	<u>Remark</u>
Irradiance source	LEDs	LEDs	LEDs	LEDs	
Anatomical sites	Entire Face	Entire Face	Entire Face	Entire Face	
Wavelength	SKB-1909: Red light: 630nm±10nm Blue light:460nm±10nm SKB-1703: Blue light:460nm±10nm SKB-1803, SKB-1809, SBK-2109,SKB-2129, SKB-2208PRO and SKB-2209: Red light: 630nm±10nm	605nm 625nm 465nm	415±10nm blue light 605±10nm amber light 630±10nm red light	<u>Blue light: 415±10 nm</u> <u>Red light: 630±10 nm</u>	<u>Same</u>
Power Intensity	SKB-1909: Red light: 2.3mW/cm <sup>2</sup> Blue light:1.33mW/cm <sup>2</sup> SKB-1703: Blue light:1.33mW/cm <sup>2</sup> SKB-1803, SKB-1809, SBK-2109, SKB-2129, SKB-2208PRO and SKB-2209: Red light: 2.3mW/cm <sup>2</sup>	Red 2.45mW/cm <sup>2</sup> Blue 1.33mW/cm <sup>2</sup>	Red light: 2.5mW/cm <sup>2</sup> Amber light: 15mW/cm <sup>2</sup> Blue light: 1.4mW/cm <sup>2</sup>	<u>Blue light:</u> <u>25 mw /cm<sup>2</sup>±10%</u> <u>Red light:</u> <u>45mw /cm<sup>2</sup>±10%</u>	<u>Same</u>
Hot compress temperature	SKB-1809/SKB-2209: THERMO(Hot compress):	/	Hot compress and vibration function: 40±1°C	<u>Warming function: 44±2°C</u>	<u>Similar</u>

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference device</u>	<u>Remark</u>
	35.5~38.5°C±0.5°C SKB-1909: THERMO(Hot compress): 35.5~38.5°C±0.5°C THERMO+VIB(Hot compress and vibration function): 39±1°C				
Motor vibration	SKB-1703,SKB-1809,SKB-1909,SKB-2209:  Motor vibration	/	Motor vibration	<u>Micro motor</u>	<u>Same</u>
Electrical safety	IEC 60601-1 IEC 60601-1-11 IEC 62471 IEC 60601-2-57 IEC 60601-1-2 IEC 62133-2	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-6 IEC 62471 IEC 60601-2-57 IEC 60601-1-2 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	<u>IEC 60601-1</u> <u>IEC 60601-1-2</u> <u>IEC 60601-1-11</u> <u>IEC 60601-2-10</u> <u>IEC 60601-2-57</u>	<u>Same</u>
Biocompatibility feature	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10 and ISO 10993-23	All patient contacting materials are complied with ISO 10993-1	ISO 10993-5 ISO 10993-10 ISO 10993-23	<u>ISO 10993-5</u> <u>ISO 10993-10</u>	<u>Same</u>

## **VII. Performance Data**

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

### **1) Biocompatibility Safety**

The materials of the patient-directly contacting components of the subject device is performed the biocompatibility evaluation 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 –Part 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 and EMC Safety**

Electrical safety and Eye safety testing was performed to, and passed, the following standards:

- 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 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 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 60601-2-57:2011 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, cosmetic and aesthetic use
- IEC 62133-2:2022 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 62471:2006 Photobiological safety of lamps and lamp systems

### **4) Software Verification and Validation**

Software documentation consistent with *Basic Documentation* 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.

### **Summary**

Based on the above performance as documented in this application, the subject device was found to have a safety and effectiveness profile that is similar to the predicate devices.

### **VIII. Conclusions**

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design and performance, it can be concluded that the Multi-functional Facial Beauty Device is substantially equivalent to the legally marketed predicate devices.