December 23, 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: K252146
Trade/Device Name: Multi-functional Facial Beauty Device (SKB-1703,SKB-1803,SKB-1909, SKB-2003 SKB-2109,SKB-2129,SKB-2208PRO, SKB-2209)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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.	K252146

Please provide the device trade name(s).

Multi-functional Facial Beauty Device (SKB-1703,SKB-1803,SKB-1909, SKB-2003 SKB-2109,SKB-2129,SKB-2208PRO, SKB-2209)

Please provide your Indications for Use below.

Multi-functional Facial Beauty Device is a handheld portable device for over the counter aesthetic use including facial stimulation through MC(micro-current) mode.

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 of K252146

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

Date: 2025-12-19

I. Submitter

Shenzhen Siken 3D Technology Development Co., Ltd.
Room 1104, Building 2, Xinweirun High-tech Park, No. 162, Shajiang Road, Xitou Community, Shajiang Road, Songgang Street, Bao'an District, Shenzhen, Guangdong, China.
Post code: 518105
Tel.: +86-0755-27697523

Jing Quan Liu
Title: Management representative
Tel.: +86-0755-27697523
Email:1550420556@qq.com

II. Device

Name of Device: Multi-functional Facial Beauty Device
Model(s): SKB-1703,SKB-1803,SKB-1909,SKB-2003,SKB-2109,SKB-2129,SKB-2208PRO, SKB-2209
Common or Usual Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Classification Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NFO
Regulation Number: 21 CFR 882.5890

III. Predicate Device & Reference Device

Primary predicate device:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
Xtreem Pulse	PureLift Pro Edition	K230506	June 21, 2023

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
Shenzhen Aozemei Technology Co. Ltd	Micro-current Facial Beauty Device	K243430	December 19, 2024
BELEGA Co., Ltd.	Beagank 4T Plus	K233010	November 21, 2023

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. (Cleared under K252142).

c. Blue LED irradiation.(Cleared under K252142).

d. Hot compress and vibration function.(The vibration is classified as class I and not need for 510K, and the hot compress(39℃±0.5℃) is not for medical purpose).

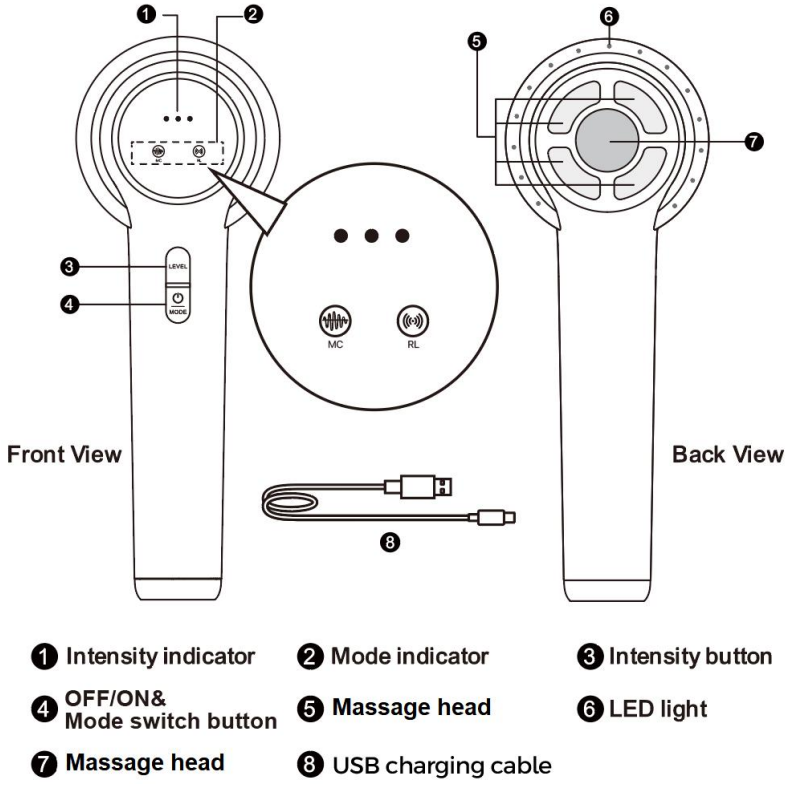
e. Hot compress function.(The hot compress(35.5℃～38.5±0.5℃) is not for medical purpose).

f. Vibration function(motor vibration).(The vibration is classified as class I and not need for 510K).

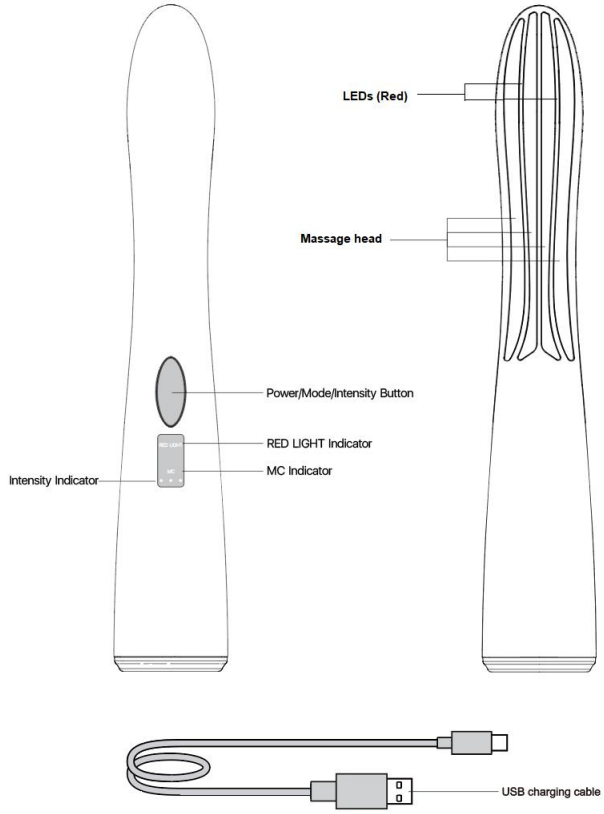
Each mode of the device is independent from all other modes of the Multi-functional Facial Beauty Device.

The Multi-functional Facial Beauty Device consists of a main unit, USB charging cable, components shown as following illustration: (Here takes model SKB-2109 and model SKB-2129 as examples)

SKB-2109:



SKB-2129:



V. Indications for Use

Multi-functional Facial Beauty Device is a handheld portable device for over the counter aesthetic use including facial stimulation through MC(micro-current) mode.

VI. Comparison of Technological Characteristics With the Predicate Device

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

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
510(k) Number	K252146	K230506	K243430	K233010	/
Trade name	Multi-functional Facial Beauty Device	PureLift Pro Edition	Micro-current Facial Beauty Device Model: AM-810B, AM-810W, AM-812B, AM-812W	Beagank 4T Plus	/
Manufacturer	Shenzhen Siken 3D Technology Development Co., Ltd	Xtreem Pulse	Shenzhen Aozemei Technology Co., LTD	BELEGA Co., Ltd.	/
Regulation number	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	Same
Product code	NFO	NFO	NFO	NFO	Same
Device classification	II	II	II	II	Same
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Indication for use/ Intended use	Multi-functional Facial Beauty Device is a handheld portable device for over the counter aesthetic use including facial stimulation through MC(micro-current) mode.	Intended for facial stimulation and indicated for over-the-counter cosmetic use.	Micro-current Facial Beauty Device is a handheld portable device for over the counter aesthetic use including facial use including facial and neck simulation.	The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.	Same
Handheld or stationary	Hand-held Type	Hand-held Type	Hand-held Type	Hand-held Type	Same

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
Treatment area	Face	Face	Face and neck	Face and neck or body	Same
Number of output modes	1	1	1	4	Same
Number of out channels	1	1 output channel	1	1	Same
Regulated current or regulated voltage	Regulated current	Regulated current	unknown	Voltage	Same
Software/ Firmware/ Microprocessor Control	Yes	Yes	Yes	Yes	Same
Automatic Shut off	Yes	Yes	unknown	Yes	Same
Indicator Display	Yes	Yes	unknown	unknown	Same
Timer range	10 minutes	10 minutes only	MS-Micro current stimulation mode: It is recommended to use the product 10-15 minutes at a time / 2-3 times a week.	Maximum 5 minutes	Same
Type of protection	Type BF	Type BF	unknown	Type BF	Same
On/off status	Yes	Yes	unknown	unknown	Same

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
Waveform	Pulse-symmetric, biphasic, rectangular wave	Pulses Monophasic, alternating polarity	Biphasic pulsed square wave	Rectangle, biphasic asymmetric	Similar Note 1
Shape	Rectangular Pulses	Rectangular Pulses	Square Pulses	Rectangle, biphasic asymmetric	Same
Maximum output voltage	16Vpp @500Ω 28Vpp @ 2kΩ 37Vpp @ 10kΩ	16Vpp(@500Ω) 27.0Vpp(@2kΩ) 38.4Vpp(@10kΩ)	225mV @500Ω 900mV @ 2kΩ 3.6mV @ 10kΩ	Mode 1: 127mV (0.12V)@500Ω 515mV (0.51V)@2KΩ 1.83V@10KΩ Mode 2: 110mV(0.11V)@500Ω 507mV(0.50V)@2KΩ 1.87V@10KΩ Mode 3: 16.6V@500Ω 21.0V@2KΩ 22.5V@10KΩ Mode 4: 15.3V@500Ω 21.2V@2KΩ 22.9V@10KΩ	Same

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
Maximum output current	32mA @500Ω 14mA @ 2kΩ 3.7mA @10kΩ	7.7mA(@500Ω) 3.6mA(@2kΩ) 1.0mA(@10kΩ)	450μA @500Ω 450μA @ 2kΩ 360μA @10kΩ	Mode 1: 0.19mA@500Ω 0.18mA@2KΩ 0.16mA@10KΩ Mode 2: 0.45mA@500Ω 0.39mA@2KΩ 0.24mA@10KΩ Mode 3: 30.8mA@500Ω 8.52mA@2KΩ 2.26mA@10KΩ Mode 4: 31.4mA@500Ω 8.60mA@2KΩ 2.15mA@10KΩ	Similar Note 2
Output tolerance	+/- 10%	+/- 1mA	+/-10%	+/-15%	Same
Pulse Width	4μs	4μs	4ms	Mode 1: 265μs	Same

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
				Mode 2: 265μs Mode 3: 274μs Mode 4: 610μs	
Frequency (Hz)	1.6kHz	1.37kHz～1.73kHz	57Hz	Mode 1: 3.80kHz Mode 2: 3.80kHz Mode 3: 3.65kHz Mode 4: 1.64kHz	Similar Note 3
Symmetrical phases	Yes	Not multiphasic	Yes	No	Same
Net Charge (μC per pulse train)	0μC@500Ω	0μC per pulse train	0μC@500Ω	Mode 1: 0.025μC@500Ω Mode 2: 0.025μC@500Ω Mode 3: -1.3μC@500Ω Mode 4: 0μC@500Ω	Same
Maximum Phase Charge (μC)	0.0774μC@500Ω	4.97μC@500Ω	2.3619μC@500Ω	Mode1: 0.059μC@500Ω Mode 2: 0.025μC@500Ω Mode 3: 2.2μC@500Ω Mode 4: 0.29μC@500Ω	Difference Note 4
Maximum current Density (mA/cm^2)	0.4mA/cm^2@500Ω	7.5mA/cm^2@500Ω	AM-810B, AM-810W: 0.10mA/cm^2@500Ω AM-812B, AM-812W:	With a wet cotton pad (Purified water)	Difference Note 5

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
			0.06mA/cm^2@500Ω	Mode 1: 0.15~1.36mA/cm^2@500Ω Mode 2: 0.10~0.92mA/cm^2@500Ω Mode 3: 4.26~38.43mA/cm^2@500Ω Mode 4: 3.13~28.21mA/cm^2@500Ω	
Maximum Power Density	0.26mW/cm^2@500Ω	29250μW/cm^2	AM-810B, AM-810W: 0.0117mW/cm^2@500Ω AM-812B, AM-812W: 0.0072mW/cm^2@500Ω	With a wet cotton pad: Mode 1: 11.39μW/cm^2@500Ω Mode 2: 33.87μW/cm^2@500Ω Mode 3: 1124.0μW/cm^2@500Ω	Difference Note 5

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
				Mode 4: 556.96μW/cm^2@500Ω	
Electrical safety	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-10 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-10 IEC 62133-2	IEC 60601-1 IEC 60601-1-2	Same
Biocompatibility feature	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10 and ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same

Note 1:

Though the waveform of the subject device is little different from the primary predicate device , but it is the same as predicate device 1(K243430). Therefore, this difference will not any raise safety or effectiveness issues.

Note 2:

The maximum output current of the subject device is close to the mode 4 of predicate device 2 (K233010). The subject device has been tested for electrical safety as per IEC60601-1, IEC 60601-2-10, so this difference does not impact its safety and effectiveness.

Note 3:

Though the Frequency of the subject device is is little different from the primary predicate device, however it is within the rang of the primary predicate device. So this difference will not any raise safety or effectiveness issues.

Note 4:

There is a difference in the maximum phase charge between the subject devices and the primary predicate device, however the maximum

phase value is within the range of the predicate device 2. Therefor this difference will not any raise safety or effectiveness issues.

Note 5:

Regarding the Maximum current density and the Maximum power density, the maximum current density of the subject device (0.4mA/cm^2) is within the rang of predicate devices. And the 0.4mA/cm^2 is far less then the limit of 2mA/cm^2 specified in IEC 60601-2-10. The value of Maximum power density of subject device is within the rang of the predicate devices. The subject device has provide adequate electrical safety and performance testing, which were conducted according to applicable standards for nerve and muscle stimulators (including IEC 60601-1 and IEC 60601-2-10) as well as lab bench performance evaluation. Therefore, these difference will not any raise safety or effectiveness issues.

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 –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 and EMC Safety

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

- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 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 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.
- IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

3) 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, materials and performance, it can be concluded that the Multi-functional Facial Beauty Device is as safe, as effective, and performs as well as the legally marketed predicate devices.