December 19, 2024

Shenzhen Aozemei Technology Co. Ltd
Riley Chen
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K243430
Trade/Device Name: Micro-current Facial Beauty Device (AM-810B, AM-810W, AM-812B, AM-812W)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: November 5, 2024
Received: November 5, 2024

Dear Riley Chen:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
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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)*

K243430

Device Name

Micro-current Facial Beauty Device (AM-810B, AM-810W, AM-812B, AM-812W)

Indications for Use *(Describe)*

Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne. (cleared under K241718)
Micro-current Facial Beauty Device is a handheld portable device for over the counter aesthetic use including facial and neck stimulation.

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

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

I. Submitter

Company name: Shenzhen Aozemei Technology Co., LTD
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Contact person: Zemin Wu
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Email: 80728261@qq.com
Date: 2024.11.5

II. Subject Device

Name of Device: Micro-current Facial Beauty Device
Model(s): AM-810W, AM-810B, AM-812W, AM-812B
Common or Usual Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NFO
Regulation Number: 21 CFR 882.5890

III. Predicate Device

No.	Manufacturer	Device name	Product code	510(k) Number	Cleared Date
1.	Heat In A Click	2 Face / Face Evolution	NFO, OHS, OLP	K171821	April 26, 2018
2.	Li-Tek Electronics Technology Co., Ltd.	Micro-current vibration facial cold and hot service Model: TPML-100	NFO, OLP	K213039	May 25, 2022
3.	BELEGA Co., Ltd.	BEAGANK 4T PLUS	NFO	K233010	Nov. 21, 2023

IV. Device Description

The Micro-current Facial Beauty Device is a portable, non-sterile, reusable device designed to achieve the aesthetic effect. It consists of main unit, charging cable, cleaning flannelette, storage bag, instrument base 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 two massage heads, and three LED light mode (Amber/ Red/ Blue lights are output independently) to provides following functions:

a. Amber, Red and Blue LED irradiation function. The device outputs amber light with the wavelength of 605±10nm, and red light with the wavelength of 630±10nm. It is used to illuminate facial skin with narrow spectral bandwidth light and treat facial wrinkles. Also, it outputs blue light with the wavelength of 415±10nm and is used to illuminate facial skin with narrow spectral bandwidth light and treat mild to moderate inflammatory acne. (Cleared under K241718)

b. Hot compress and vibration function. The device generates different intensity of vibration by a builtin motor to relax the facial skin, and also, the massage head is heated to 40±1℃, making the facial skin feel warm to relax and soothe the facial skin. (The vibration is classified as class I and not need for 510K, and the hot compress is not for medical purpose). (Cleared under K241718)

c. MS-Micro current stimulation function. The device has two electrode massage heads to do facial stimulation.

V. Indications for Use

Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne. (cleared under K241718)

Micro-current Facial Beauty Device is a handheld portable device for over the counter aesthetic use including facial and neck stimulation.

VI. Comparison of Technological Characteristics With the Predicate Device

The Micro-current Facial Beauty Device has the same intended use as the predicates. The technological characteristics, features, specifications, materials are similar to the predicate devices. Any minor differences between the subject device and the listed predicate 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 for its intended use.
Therefore, the Micro-current Facial Beauty Device may be found substantially equivalent to its predicate devices.

Elements of Comparison	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Remark
Device Name and Model	Micro-current Facial Beauty Device Model: AM-810B, AM-810W, AM-812B, AM-812W	2 Face / Face Evolution	Micro-current vibration facial cold and hot service Model: TPML-100	BEAGANK 4T PLUS	/
510(k) Number	Pending	K171821	K213039	K233010	/
Product code	NFO	NFO, OHS, OLP	NFO, OLP	NFO	Same
Device classification	Class II	Class II	Class II	Class II	Same
OTC or prescription	OTC	OTC	OTC	OTC	Same
Intended Use	Micro-current Facial Beauty Device is a handheld portable device for over the counter aesthetic use including facial and neck stimulation.	2 Face / Face Evolution is a hand-held device for over-the counter aesthetic purposes. (1) The EMS mode is indicated for facial stimulation; (2) The Photon mode: The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	Micro-current 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 for the over the counter aesthetic use.	The BEAGANK 4T PLUS is a handheld portable device for overthe-counter aesthetic use including facial and neck stimulation or body skin stimulation.	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Remark
Dimensions	AM-810B, AM-810W: 135*85*39mm AM-812B, AM-812W: 110*92*68mm	158mm*56mm*51.5mm	188(L)×50(W)×55(H)mm	/	Different
Weight	AM-810B, AM-810W: 118g AM-812B, AM-812W: 130g	200g	233g	136g	
Treatment area	Face and neck	Entire Face	Facial skin	Facial and neck or body skin	Same
Software control	YES	YES	YES	YES	Same
Handheld	YES	YES	YES	YES	Same
Power source	Adapter input: 5V⎓0.5A Internal battery: 3.7V/600mAh	DC 3.7V 2200mAh	Charger (not included) input: DC 5V, 1A Internal battery: 3.7Vd.c. 900mAh	Internal rechargeable Lithium-ion battery	Similar
Battery	Lithium battery	Battery	Lithium battery	Lithium battery	Same
Micro-current Stimulation Function					
Waveform Type	Biphasic pulsed square	Pulsed Biphasic, Modulated	Bi-phase square-wave pulse	Rectangle, biphasic	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Remark
	wave	Square		asymmetric	
Maximum Output Voltage	225mV @500Ω 900mV @2kΩ 3.60V @10kΩ	310mV @ 500Ω 1.16V @ 2kΩ 5.56V @ 10kΩ	225 mV @500Ω, ±10% 900 mV @2kΩ, ±10% 3.86 V @10kΩ, ±10%	Mode 1: 127mV@500Ω, ±15% 515mV@2kΩ, ±15% 1.83V@10kΩ, ±15%	Similar
Maximum Output Current	450μA @500Ω 450μA @2kΩ 360μA @10kΩ	620μA @ 500Ω 580μA @ 2kΩ 556μA @ 10kΩ	450 μA @500Ω, ±10% 450 μA @2kΩ, ±10% 386 μA @10kΩ, ±10%	Mode 1: 0.19mA@500Ω,±15% 0.18mA@2kΩ, ±15% 0.16mA@10kΩ,±15%	
Pulse Width	4ms	60ms	4ms	Mode 1: 265μs	Same
Output Frequency	57Hz	8.333Hz	57±3Hz	Mode 1: 3.80kHz	Same
Net charge	0 μC @ 500Ω	/	0 μC @ 500Ω	Mode 1: 0.025μC	Same
Maximum Current Density	AM-810B, AM-810W: 0.10mA/cm^2@500Ω AM-812B, AM-812W: 0.06mA/cm^2@500Ω	0.330mA/cm^2 @500 Ω (The Minimum Electrode Size: 2.91cm^2)	0.49mA/cm^2@500Ω	Mode 1: Standard:0.15mA/cm^2 Scalp: 0.53mA/cm^2	Similar

Elements of Comparison	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Remark
				Small: 1.36mA/cm^2	
Maximum Power Density	AM-810B, AM-810W: 0.0117mW/cm^2@500Ω AM-812B, AM-812W: 0.0072mW/cm^2@500Ω	4.34μW/cm^2 @500Ω (The Minimum Electrode Size: 2.91cm²)	0.20mW/cm^2@ 500Ω	Mode 1: 8.51μW/cm^2 With a wet cotton pad 11.39μW/cm^2	
Treatment frequency	• MS-Micro current stimulation mode: It is recommended to use the product 10-15 minutes at a time / 2-3 times a week.	EMS Mode (5 minutes) Photon Mode (5~7 minutes)	Hold treatment face in contact with skin. Apply blue light for 3minutes per skin area, followed by red light for 3 minutes per skin area. Can be used daily. Apply EMS micro-current for 15 minutes per day. Can be used for 2-3 times per week.	5 minutes	Same
Main Materials	ABS, PC	ABS Plastic & Stainless Steel	PC, ABS, Stainless steel (SUS 304)	ABS	Different, but solved by biocompatibility test

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 Micro-current 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 recognized 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 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Medical Electrical Equipment –Part 1-11: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- 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

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.