October 28, 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: K241718
Trade/Device Name: Micro-current Facial Beauty Device (AM-810B, AM-810W, AM-812B, AM-812W)
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: June 11, 2024
Received: June 14, 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.

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,

Yan Fu -S

Digitally signed by Yan Fu -S
Date: 2024.10.28 15:23:56 -04'00'

for

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

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.

510(k) Number *(if known)*
K241718

Device Name
Micro-current Facial Beauty Device (Model(s): AM-810W, AM-810B, AM-812W, AM-812B)

Indications for Use *(Describe)*
Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne.

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 - K241718

"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
Title: General Manager
Tel.: +86-150 1922 0323
Email: 80728261@qq.com
Date: 2024.10.10

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: Over-The-Counter Powered Light Based Laser For Acne
Light based over the counter wrinkle reduction
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810

III. Predicate Device and Reference Device

- 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.	Galactic Beauty, LLC	MMSphere™	OHS, OLP	K190443	Jun. 24, 2019
3.	Shenzhen SUNGPO HI-TECH Electronic Co., Ltd	LED Facial Mask	OHS, OLP	K230351	May 5, 2023

- Reference Device

No.	Manufacturer	Device name	Product code	510(k) Number	Cleared Date
1.	STG24 CO.,LTD.	LED MASK EXCLUSIVE MD	OHS, OLP	K232795	Dec. 7, 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.

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).

V. Indications for Use

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

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	Reference Device	Remark
Device Name and Model	Micro-current Facial Beauty Device Model: AM-810B, AM-810W, AM-812B, AM-812W	2 Face / Face Evolution	MMSphere™	LED Facial Mask/ MZ-01, NEWKEY-01, SP-FM-01	LED MASK EXCLUSIVE MD Model: ME-M20M4	/
510(k) Number	K241718	K171821	K190443	K230351	K232795	/
Regulation number	878.4810	882.5890, 878.4810	878.4810	878.4810	878.4810	Same
Product code	OHS, OLP	NFO, OHS, OLP	OHS, OLP	OHS, OLP	OHS, OLP	Same
Intended Use	Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne.	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.	MMSphereTM 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 MMSphereTM is designed to be used for 20 minute treatments three to seven times per week.	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.	LED MASK EXCLUSIVE MD is an over the counter device that is indicated for the treatment of full face wrinkles with red light and infrared light and treat mild to moderate acne vulgaris of the face.	Same
Treatment area	Face	Entire Face	Facial skin	Face	Face	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Reference Device	Remark
Software control	YES	YES	YES	YES	Yes	Same
Handheld	YES	YES	Handheld and stationary	No	No, mask type	Same
Power source	Adapter input: 5V⎓0.5A Internal battery: 3.7V/600mAh	DC 3.7V 2200mAh	/	An external adapter Input: AC 100-240V, 50-60Hz 0.2A Output: DC 12V 0.5A	/	Similar
Battery	Lithium battery	Battery	Lithium battery	/	Battery	Same
Light Therapy Function						
Light source	Light Emitting Diodes (LED)	LED	Light Emitting Diodes (LED)	Light Emitting Diodes (LEDs)	LED	Same
Wavelength	415±10nm blue light 605±10nm amber light 630±10nm red light	Red Light: 630nm±3nm Blue Light: 415nm±3nm	605nm, 625nm, 465nm	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm	415nm 655nm 845nm	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Predicate Device 1	Predicate Device 2	Reference Device	Remark
Irradiance (mW/cm^2)	Red light: 2.5mW/cm^2 Amber light: 15mW/cm^2 Blue light: 1.4mW/cm^2	Red light: 73.26mW/cm^2±10% Blue light: 64.10mW/cm^2±10%	Red: 2.45 mW/cm^2 Blue: 1.33 mW/cm^2 Amber: Not publicly available	Blue: 15~63mW/cm^2 Red: 31~75mW/cm^2 Amber: 15~42mW/cm^2	- Red: 1mW/cm^2 + NIR: 1mW/cm^2 - Blue: 1mW/cm^2	Similar
Main Materials	ABS, PC	ABS Plastic & Stainless Steel	/	ABS and PC plastic	/	Different, but solved by biocompatibility test
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Comply with ISO 10993-1	Comply with ISO10993-1, ISO10993-5 and ISO10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-11	Same
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC60601-2-10 IEC60601-2-57	ANSI/AAMI ES 60601-1 EN 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57	ES 60601-1 IEC 60601-2-57 IEC 60601-1-11 IEC 60601-1-2	Same

VII.Performance Data

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

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the 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 60601-1:2005/AMD1:2012/AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020 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 :2015/AMD1:2020 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 60601-2-83:2019 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62133-2:2017, 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 ***moderate 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.