November 19, 2025

Shenzhen Dachi communication Co.,Ltd.
% Bing Huang
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center,
No. 3101-90 Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K252642
Trade/Device Name: Microcurrent Facial Device (CEC101, EEI101)
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
Dated: August 21, 2025
Received: August 21, 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.11.19 14:46:04 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252642

Device Name
Microcurrent Facial Device (CEC101, EEI101)

Indications for Use *(Describe)*
EC101:
Microcurrent Facial Device is intended for facial stimulation for over-the-counter aesthetic use.
The light treatment of Microcurrent Facial Device is indicated for :
- Red light is intended for the treatment of facial wrinkles.
- Blue light is intended for the treatment of mild to moderate inflammatory acne.

EEI101:
Microcurrent Facial Device is intended for facial, neck and body skin stimulation for over-the-counter aesthetic use.
The light treatment of Microcurrent Facial Device is indicated for:
- Red light is intended for the treatment of facial wrinkles.
- Blue light is intended for the treatment of mild to moderate inflammatory acne.
- Mixed light (Red and Blue) is intended for the treatment of 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 #K252642

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

Date: 2025-11-19

I. Submitter

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II. Device

Name of Device: Microcurrent Facial Device
Model(s): CEC101, EEI101
Common or Usual Name: Light Based Over The Counter Wrinkle Reduction
Over-The Counter Powered Light Based Laser 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 890.4810

III. Predicate Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
Shenzhen Aozemei Technology Co., LTD	Micro-current Facial Beauty Device(Model(s): AM-810W, AM-810B, AM-812W, AM-812B)	K241718	October 28, 2024
BEMER Int. AG	BEMER Therapy Systems Evo(B.Light Clear Evo and B.Light Restore Evo)	K223919	September 23, 2023

Reference device:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
STG24 CO.,LTD.	Led Mask Platinum Exclusive MD	K232795	December 7, 2023

SHENZHEN BORRIA TECHNOLOGY CO.,LTD	LED Therapy Mask (MN1, M226)	K242385	April 7, 2025

IV. Device Description

The Microcurrent Facial Device probe is designed for optimal contact with the face. The device has two different microcurrent modes that differ in how the probe switches. Users can adjust settings for personalized comfort by pressing the mode button. The microcurrent mode intensity starts from (0) to (9).(Cleared under K244004)

The device also outputs blue light with the wavelength of 415+/-10nm and red light with the wavelength 622+/-10nm and delivers to the skin of the face to achieve the therapeutic effects， such as improving mild to moderate acne on the face.

The Microcurrent Facial Devices unit contains a main board and a rechargeable battery. The enclosure is made of medical-grade biocompatible plastic and the probe is made of irregularly shaped stainless steel.

Model CEC101 have “Phototherapy mode”, “CLEANING mode”,”PENETRATION mode”, “LIFTING mode” and “COOL mode” five modes. The “CLEANING mode”,”PENETRATION mode”, “LIFTING mode” and “COOL mode” modes have cleared under K244004.

Model EEI101 have “Phototherapy mode”, “Face mode”, “Neck mode”, and “Body mode” four modes. The “Face mode”, “Neck mode”, and “Body mode” have cleared under K244004.

V. Indications for Use

CEC101:
Microcurrent Facial Device is intended for facial stimulation for over-the-counter aesthetic use.
The light treatment of Microcurrent Facial Device is indicated for :

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

EEI101:
Microcurrent Facial Device is intended for facial, neck and body skin stimulation for over-the-counter aesthetic use.
The light treatment of Microcurrent Facial Device is indicated for:

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

VI. Comparison of Technological Characteristics With the Predicate Device

Microcurrent Facial Device is compared with the following predicate devices and reference devices in terms of intended use, design, specifications, materials and performance:

Comparison Elements	Subject Device	Predicate device 1	Predicate device 2	Reference device1	Reference device 2	Remark
K number	**K252642**	**K241718**	**K223919**	**K232795**	**K242385**	**/**
Trade name/Model	Microcurrent Facial Device Models: CEC101, EEI101	Micro-current Facial Beauty Device Model: AM-810B, AM-810W, AM-812B, AM-812W	BEMER Light Therapy System(B. Light Clear Evo, B.light Restore Evo)	LED MASK EXCLUSIVE MD(Model:ME-M20M4)	LED Therapy Mask (MN1, M226)	/
Manufacturer	Shenzhen Dachi Communication Co., Ltd..	Shenzhen Aozemei Technology Co., LTD	BEMER International, AG	STG24 CO.,LTD.	SHENZHEN BORRIA TECHNOLOGY CO.,LTD	/
Device Classification Name	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Same
Review panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same
Regulation number	878.4810	878.4810	878.4810	878.4810	878.4810	Same
Device class	II	II	II	II	II	Same
Product code	OHS, OLP	OHS, OLP	OHS/OLP	OLP	OHS, OLP, ILY	Same
Indication for use/Intended use	CEC101: The light treatment of Microcurrent Facial Device is indicated for : • Red light is intended for the treatment of facial	Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne.	B.Light Clear Evo: The device is intended for over-the-counter (OTC) use to treat patients with mild to moderate acne vulgaris on the face. B.Light Restore Evo: Use	LED MASK EXCLUSIVE MD is an over the counter device that is indicated for the treatment of full face wrinkles with red light	Red light: Treatment of full- face wrinkles. Blue light (only suitable model M226 and MN1 LED Facial Mask): Treatment of mild to moderate inflammatory	Same

Comparison Elements	Subject Device	Predicate device 1	Predicate device 2	Reference device1	Reference device 2	Remark
K number	K252642	K241718	K223919	K232795	K242385	/
	wrinkles. • Blue light is intended for the treatment of mild to moderate inflammatory acne. EEI101: The light treatment of Microcurrent Facial Device is indicated for: • Red light is intended for the treatment of facial wrinkles. • Blue light is intended for the treatment of mild to moderate inflammatory acne. • Mixed light (Red and Blue) is intended for the treatment of mild to moderate inflammatory acne.		of light-based treatment to reduce wrinkles on the face.	and infrared light and treat mild to moderate acne vulgaris of the face.	acne. Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. Mixed light: Treatment of full face wrinkles.	
OTR or prescription	OTC	OTC	OTC	OTC	OTC	Same

Comparison Elements	Subject Device	Predicate device 1	Predicate device 2	Reference device1	Reference device 2	Remark
K number	**K252642**	**K241718**	**K223919**	**K232795**	**K242385**	/
Treatment site	Face	Face	Face	Face	Face and Neck	Same
Power Supply	Input:5V ⎓ 1A; Output:3.7V CEC101: 3.7V/2600mAh EEI101: 3.7V/2600mAh	Adapter input: 5V 0.5A Internal battery: 3.7V/600mAh	Control unit : Input voltage 100 -240 V AC / 50 - 60 Hz, 15 VDC / 2A Applicator:15 V AC	Not publicly available	Input：DC 5V, 1A Built-in rechargeable lithium battery: DC 3.7V 2500mAh	Different **Note 1**
Battery	Lithium-ion	Lithium battery	Li-Ion battery	Not publicly available	Lithium battery	Same
Light Therapy Function						
Light source	Light Emitting Diodes(LED)	Light Emitting Diodes(LED)	Light Emitting Diodes(LED)	LED	Light Emitting Diodes(LED)	Same
Wavelength	Blue light: 415±10 nm Red light: 622±10 nm	415±10nm blue light 605±10nm amber light 630±10nm red light	B.Light Clear Evo: Red: 645nm±20nm Blue:465nm±20nm B.Light Restore Evo: IR: 860nm±20nm Red: 645nm±20nm	415nm, 655nm, 845nm	Red: 630nm±5nm Blue: 470 nm±5nm Near-Infrared: 850nm±5nm Mixed light: 630nm and 850nm	Same
Power irradiance	**CEC101:** Blue light: 0.75mW/cm^2 Red light: 0.77mW/cm^2 **EEI101:** Blue light: 1.12mW/cm^2 Red light: 1.43mW/cm^2 Mixed light： 1.81mW/cm^2	Red light: 2.5mW/cm^2 Amber light: 15mW/cm^2 Blue light: 1.4mW/cm^2	B.Light Clear Evo: Red: 0.76mW/cm^2 Blue:1.20mW/cm^2 Total: 2 mW/cm^2 B.Light Restore Evo: IR: 1.40mW/cm^2 Red: 0.56mW/cm^2 Total:2mW/cm^2	Red: 1mW/cm^2+NIR:1mW/cm^2 Blue :1mW/cm^2	Red: 0.89~2.55mW/cm$_2$ Blue: 1.44~4.09mW/cm$_2$ Near-Infrared: 1.83~3.05mW/cm$_2$ Mixed light: 0.95~2.64mW/cm$_2$	Similar **Note 2**

Comparison Elements	Subject Device	Predicate device 1	Predicate device 2	Reference device1	Reference device 2	Remark
K number	**K252642**	**K241718**	**K223919**	**K232795**	**K242385**	**/**
Main Materials	ABS, Stainless steel	ABS, PC	Not publicly available	Not publicly available	Not publicly available	Different **Note 3**
Dimension	CEC101:193.68*68*60mm EEI101: 202.6*69.32*62mm	Not publicly available	System： 21cm*15cm*4.3cm Applicator: 12cm*12cm*2.5cm	Not publicly available	MN1: LED Facial Mask: 300*208.5*5.5mm LED Neck Mask: 338.5*249.7*5.5mm M226: LED Facial Mask: 300*208.5*5.5mm	Different **Note 3**
Net Weight	CEC101: 266g EEI101: 230g	Not publicly available	System：926g Applicator: 0.12kg	Not publicly available	Not publicly available	Different **Note 3**
Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-57	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 60601-2-83 IEC 62471 IEC 62133-2	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1	ISO 10993-11 ISO 10993-5 ISO 10993-10	All body-contacting materials are complied with ISO 10993-5, ISO 10993-10 and ISO 10993-23	Same

Comparison in Detail(s):

Note 1:

The power supply for the subject device is different from that of the predicate device, however the lithium battery of the subject device has passed IEC 62133-2 test, so this difference should not raise any safety/effectiveness questions.

Note 2:

Though the irradiance of subject device is a little different from the predicate devices and the reference device, the irradiance of the subject device can be basically covered by the predicate devices and reference devices' range and they all comply with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Note3:

Though the dimension and weight are little different from the predicate device and reference device, this difference is insignificant and do not raise any safety or effectiveness problems. And main materials is a little different from the predicate device 1, but the subject device has passed biocompatibility test, so this difference do not raise any safety of effectiveness problem.

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 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 62133-2 Edition 5.0 2021-09, 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.
- 60601-2-83:2022, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment.

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 and performance, it can be concluded that the Microcurrent Facial Device is as safe, as effective and performs as well as the legally marketed predicate devices and reference devices.