July 10, 2025

Shenzhen Dachi communication Co.,Ltd.
% Jilan Luo
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: K244004
Trade/Device Name: Microcurrent Facial Device (CEC101, EE0101, EEI101)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: June 20, 2025
Received: June 20, 2025

Dear Jilan Luo:

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
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OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

K244004

Device Name

Microcurrent Facial Device (CEC101, EE0101, EEI101)

Indications for Use *(Describe)*

□CEC101 and EE0101:
Microcurrent Facial Device is intended for facial stimulation for over-the-counter aesthetic use.

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

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 of K244004

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

Date: 2025-07-10

I. Submitter

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II. Device

Name of Device: Microcurrent Facial Device
Model(s): CEC101, EE0101, EEI101
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

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
BELEGA Co., Ltd.	BEAGANK 4T PLUS	K233010	November 21, 2023
Bio-Medical Research Ltd.	BMR Face	K103031	NOV 10, 2011

IV. Device Description

The Microcurrent Facial Device is a portable, non-sterile, reusable device designed to achieve the aesthetic effect. It consists of main unit, charging cable, membrane cloth, conductive gel 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.

V. Indications for Use

CEC101 and EE0101: Microcurrent Facial Device is intended for facial stimulation for over-the-counter aesthetic use.
EEI101: Microcurrent Facial Device is intended for facial, neck and body skin stimulation for over-the-counter aesthetic use.

VI. Comparison of Technological Characteristics With the Predicate Device

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

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
510(k) Number	K244004	K233010	K103031	/
Device Name and Model	Microcurrent Facial Device Models: CEC101, EE0101, EEI101	BEAGANK 4T PLUS	BMR Face	/
Regulation number	882.5890	882.5890	882.5890	Same
Classification name	Transcutaneous Electrical Nerve Stimulator for Pain Relief	Transcutaneous Electrical Nerve Stimulator for Pain Relief	Transcutaneous Electrical Nerve Stimulator for Pain Relief	
Product code	NFO	NFO	NFO	Same
Device classification	Class II	Class II	Class II	Same
OTC or prescription	OTC	OTC	OTC	Same
Intended Use	CEC101 and EE0101: Microcurrent Facial Device is intended for facial stimulation for over-the-counter aesthetic use. EEI101: Microcurrent Facial Device is intended for facial, neck and body skin stimulation for over-the-counter aesthetic use.	The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.	BMR Face is intended for facial stimulation and is indicated for Over the Counter Cosmetic Use.	Same
Method of Line Current Isolation	Type BF Applied Part	Type BF Applied Part	Not publicly available	Same

Elements of Comparison		**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
510(k) Number		K244004	K233010	K103031	/
Patient Leakage Current	NC	DC: < 1μA AC: < 1μA	DC: < 1μA AC: < 1μA	Not publicly available	Same
	SFC	DC: < 1μA AC: < 1μA	DC: < 1μA AC: < 1μA	Not publicly available	
Average DC current through electrodes when device is on but no pulses are being applied		< 1μA	< 1μA	Not publicly available	Same
Number of Output Channels		1 output channel	1 output channel	2 channels	Same
Number of Output Modes		CEC101: 2 modes EE0101: 2 modes EEI101: 3 modes	4 modes	3 modes	Similar **Note 1**
Output Intensity Level		CEC101: 10 intensity levels EE0101: 4 intensity levels EEI101: 4 intensity levels	Not publicly available	0.0 - 100.0 scale	Similar **Note 1**
Synchronous or Alternating?		NA-1 output channel	Not publicly available	Not publicly available	Same

Elements of Comparison		Subject Device	Predicate Device 1	Predicate Device 2	Remark
510(k) Number		K244004	K233010	K103031	/
Method of Channel Isolation		N/A-1 output channel	N/A	Not publicly available	Same
Regulated Current or Regulated Voltage?		Voltage Control	Voltage Control	Not publicly available	Same
Software/Firmware/Microprocessor Control?		Yes	Yes	Not publicly available	Same
Automatic Overload Trip		No	Not required due to circuit design	Not publicly available	Same
Automatic No-Load Trip		No	Not required due to circuit design	Not publicly available	Same
Automatic Shut Off		Yes	Yes	Yes	Same
User Override Control		Yes	Yes	Yes	Same
Indicator Display	On/Off Status	Yes	Not publicly available	Yes	Same
	Low Battery	Yes	Yes	Yes	Same

Elements of Comparison		**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
510(k) Number		K244004	K233010	K103031	/
	Voltage/ Current Level	Yes	Not publicly available	Not publicly available	Same
Dimensions		CEC101:193.68*68*60mm EE0101: 90*65*39mm EEI101: 202.6*69.32*62mm	Not publicly available	6.0 x 8.0 x 2.1 (cm)	Different **Note 2**
Weight		CEC101: 266g EE0101: 120g EEI101: 230g	136g	63g	Different **Note 2**
Treatment area		EEI101: Facial, neck and body skin CEC101: Facial skin EE0101: Facial skin	Face, neck and body	Facial skin	Same
Software control		YES	YES	Yes	Same
Handheld		YES	YES	Wearable	Same
Power source		Input:5V⎓1A; Output:3.7V CEC101: 3.7V/2600mAh EE0101: 3.7V/800mAh EEI101: 3.7V/2600mAh	Internal rechargeable Lithium-ion battery	3.6V rechargeable batteries	Similar **Note 3**

Elements of Comparison	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
510(k) Number	K244004	K233010	K103031	/
Waveform Type	Bi-phase square-wave pulse	Rectangle, biphasic asymmetric	biphasic symmetrical	Same
Maximum Output Voltage	CEC101: 3.77 V±10% @ 500 Ω 11.85 V±10% @ 2K Ω 33.2 V±10% @ 10K Ω EE0101: 3.57 V±10%@ 500 Ω 11.25 V±10% @ 2K Ω 31.25 V±10% @ 10K Ω EEI101: 3.54 V±10%@ 500 Ω 12.3 V±10% @ 2K Ω 34 V±10% @ 10K Ω	Mode 1: 0.12V@ 500 Ω 0.51V@ 2K Ω 1.83V@ 10K Ω Mode 2: 0.11V@ 500 Ω 0.50V@ 2K Ω 1.87V@ 10K Ω Mode 3: 16.6V@ 500 Ω 21.0V@ 2K Ω 22.5V@ 10K Ω Mode 4: 15.3V@ 500 Ω 21.2V@ 2K Ω 22.9V@ 10K Ω	15 V±10% @ 500 Ω 60 V±10% @ 2K Ω 32 V±10% @ 10K Ω	Similar **Note 4**
Maximum Output Current	CEC101: 7.54 mA±10% @ 500 Ω 5.93 mA±10% @ 2K Ω 3.32 mA±10% @ 10K Ω EE0101: 7.14 mA±10%@ 500 Ω 5.63 mA±10%@ 2K Ω	Mode 1: 0.19mA@ 500 Ω 0.18mA@ 2K Ω 0.16mA@ 10K Ω Mode 2: 0.45mA@ 500 Ω 0.39mA@ 2K Ω	30 mA±10%@ 500 Ω 30 mA±10%@ 2K Ω 3.2 mA±10%@ 10K Ω	

Elements of Comparison	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
510(k) Number	K244004	K233010	K103031	/
	3.13 mA±10%@ 10K Ω EEI101: 7.08 mA±10%@ 500 Ω 6.15 mA±10%@ 2K Ω 3.4 mA±10%@ 10K Ω	0.24mA@ 10K Ω Mode 3: 30.8mA@ 500 Ω 8.52mA@ 2K Ω 2.26mA@ 10K Ω Mode 4: 31.4mA@ 500 Ω 8.60mA@ 2K Ω 2.15mA@ 10K Ω		
Pulse Width	CEC101: 174μs EE0101: 174μs EEI101: 145μs	Mode 1: 265μs Mode 2: 265μs Mode 3: 274μs Mode 4: 610μs	160-200μs	Similar **Note 4**
Output Frequency	40Hz, 97.8Hz	Mode 1: 3.80kHz Mode 2: 3.80kHz Mode 3: 3.65kHz Mode 4: 1.64kHz	70-80Hz	Similar **Note 4**
Net charge	0 μC @ 500Ω	Mode 1: 0.025μC @ 500Ω Mode 2: 0.025μC @ 500Ω Mode 3: -1.3μC @ 500Ω Mode 4: 0 μC @ 500Ω	0 μC @ 500Ω	Same
Maximum Current Density	CEC101: 0.09mA/cm^2@500Ω EE0101: 0.45mA/cm^2@500Ω EEI101: 0.15mA/cm^2@500Ω	Mode 1: 0.15~1.36 mA/cm^2@500Ω Mode 2: 0.10~3.21 mA/cm^2@500Ω Mode 3: 4.26~220 mA/cm^2@500Ω	1mA/cm^2@500Ω	Similar **Note 4**

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
510(k) Number	K244004	K233010	K103031	/
		Mode 4: 3.13~224.3 mA/cm^2@500Ω		
Maximum Power Density	CEC101: 0.045mW/cm^2@500Ω EE0101: 0.21mW/cm^2@500Ω EEI101: 0.065mW/cm^2@500Ω	Mode 1: 8.51~11.39 μW/cm^2@500Ω Mode 2: 17.46~33.87 μW/cm^2@500Ω Mode 3: 1.124~106.6 mW/cm^2@500Ω Mode 4: 0.56~51.78 mW/cm^2@500Ω	3.91W/cm^2@500Ω	
Treatment frequency	CEC101: 3-8 minutes EE0101: 5-8 minutes EEI101: 5-8 minutes	5 minutes	5/10/20 minutes	Similar
Main Materials	ABS, Stainless steel	ABS	Plastic case built of abs, electrodes of skin conductive through adhesive hydrogel layer.	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Same
Safety and EMC	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-11 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2	Same

Comparison in Detail(s):

Note 1:

Though the number of Output Modes and Output Intensity Level are little different from the predicate devices, this difference is insignificant and do not raise any safety or effectiveness problems. Also, we have tested the product waveform parameters according to FDA guidance documents and tested the device according to the requirements of IEC 60601-2-10, the tests are all passed, so these differences do not lead to safety and effectiveness problems.

Note 2:

Though the dimension and weight are little different from the predicate devices, this difference is insignificant and do not raise any safety or effectiveness problems.

Note 3:

Although the “Power source” is slightly different from the predicate devices , they are both powered by the internal lithium battery. The lithium battery of the subject device complies with the IEC 62133-2 standard, and the device complies with IEC 60601-1 and IEC 60601-1-2 requirements, so this difference will not raise any safety or effectiveness issue.

Note 4:

Although the “Maximum Output Voltage”, “Maximum Output Current”, “Maximum Current Density(r.m.s)”, and “Maximum Power Density” of subject device are little different from the predicate devices, but their maximum and minimum are all in the range of predicate devices; “Pulse Width” and “Output frequency” of subject device are similar with the predicate device 1, we also have tested the product waveform parameters according to FDA guidance documents and tested the device according to the requirements of IEC 60601-2-10, the tests are all passed, so these differences do not raise safety and effectiveness problems.

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 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 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 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.