February 12, 2024

Body Trim Industrial Co., Ltd
% Bell Bai
Regulatory Affairs Project Manager
Shenzhen Huatongwei International Inspection Co., Ltd.
Building 7, Baiwang Idea Factory, No.1051, Songbai Road
Yangguang Community, Xili Subdistrict, Nanshan District
Shenzhen, Guangdong
China

Re: K233667
Trade/Device Name: Facial Toning device (UIC-189); Facial Toning device (UIC-589)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NFO
Dated: November 7, 2023
Received: November 15, 2023

Dear Bell Bai:

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,

Heather L. Dean -S

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

and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K233667

Device Name
Facial Toning device (UIC-189); Facial Toning device (UIC-589)

Indications for Use *(Describe)*
The Facial Toning device is intended to stimulate the face. The device is intended for cosmetic 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

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K233667
Date:	November 7th, 2023
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	BODY TRIM INDUSTRIAL CO., LTD 6F., No. 178, Huanhe Rd., Xindian Dist., New Taipei City 231034, Taiwan (R.O.C.) Tel: +886-2-22188906 E-mail: bodytrimtw@gmail.com
Contactor:	Bell Bai Shenzhen Huatongwei International Inspection Co.,Ltd. Building 7, Baiwang Idea Factory, No.1051, Songbai Road, Yangguang Community, Xili Subdistrict, Nanshan District, Shenzhen, Guangdong, China E-mail: service@regtalink.com Tel: +86-0755-86325730

2. Device Description

Proprietary Name:	Facial Toning device
Model Name:	UIC-189, UIC-589
Classification Name:	Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Product Code:	NFO
Device Class:	2
Regulation Number:	21 CFR 882.5890
Review Panel:	Neurology
Indications for use:	The Facial Toning device is intended to stimulate the face. The device is intended for cosmetic use.
Device Description:	The Facial Toning devices, which come in two models (UIC-189, UIC-589), are intended for facial stimulation and are indicated for prescription cosmetic use. The anatomical site for application of the devices are the face. UIC-189 is battery powered, has 4 output channels and has 4 operation programs. UIC-589 is AC powered, has 10 output channels and has 4 operation programs. The device is equipped with accessories of self-adhesive pads (cleared under K160081), electrode probes, electrode cables and adapters. All accessories, including self-adhesive pads, electrode probes, electrode cables and adapters can only be changed or replaced by a qualified person.

3. Predicate Device Identification

510(k) Number:	K181062	K130065
Product Name:	Ultra Facial Toning System	Beautiful Image Model 900 Facial Toning Device
Submitter:	Micro Current Technology, Inc.	Biosonic Technologies, LLC.

4. Substantially Equivalent Comparison

Table 1-

Parameters	**New Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
510(k) Number:	K233667	K181062	K130065	--
Marketing clearance date:	-	July 18, 2018	April 30, 2014	--
Device Name	Facial Toning device	Ultra Facial Toning System	Beautiful Image Model 900 Facial Toning Device	--
Model	UIC-189	/	Model 900	--
510(k) Owner	BODY TRIM INDUSTRIAL CO., LTD	Micro Current Technology, Inc.	Biosonic Technologies, LLC.	--
Intended use	The Facial Toning device is intended to stimulate the face. The device is intended for cosmetic use.	The Ultra Facial Toning System is intended to stimulate the face. The device is intended for cosmetic use.	The Beautiful Image Model 900 Facial Toning Device uses microcurrent electrical energy to stimulate facial tissues for aesthetic purposes.	Same
Type of use	Prescription Use	Prescription Use	Prescription Use	Same
Power Source(s)	3.7V 5200mAh Rechargeable lithium battery	9V alkaline battery	One 6V battery	Similar
- Method of Line Current Isolation	Type BF	Type BF	N/A	Same
- Patient Leakage Current	--	--	--	Same
- Normal Condition (μA)	< 10μA	< 10μA	N/A	
- Single Fault Condition (μA)	< 50μA	< 50μA	N/A	
Average DC current through electrodes when device is on but no pulses are being applied (μA)	< 0.01μA	< 0.01μA	None	Same
Number of Output Modes	4	2	1	Similar
Number of Output channels:	4	2	1	Same
- Synchronous or Alternating?	Synchronous	Unpublished	N/A	Similar
- Method of Channel Isolation	Current transformr Isolation	Unpublished	N/A	Same
Regulated Current or Regulated Voltage?	Current control	Unpublished	Both	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Same
Automatic Overload Trip?	No	No	Yes	Same
Automatic No-Load Trip?	No	No	Yes	Same

Automatic Shut Off?		Yes	Yes	Yes	Same
Patient Override Control?		Yes	Yes	Yes	Same
Indicator Display:	On/Off Status?	Yes	Yes	Yes	Same
	Low Battery?	Yes	Yes	Yes	Same
	Voltage/Current Level?	Yes	Yes	Yes	Same
Timer Range (minutes)		1~ 60 minutes, 1min/step	12 or 15 minutes	None	Same
Compliance with Voluntary Standards?		AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1	Same
Compliance with 21 CFR 898?		Yes	Yes	Yes	Same
Weight (grams)		Approx. 700g	Unpublished	10lbs	Similar
Dimensions [W x H x D]		220 mm*202mm*143mm	Unpublished	5.5*15.3*11.3(in.)	
Housing Materials & Construction		ABS	Unpublished	Thermoplastic	Same
Waveform		Pulsed, monophasic	Pulsed, monophasic	biphasic	Same
Shape		Rectangular, trapezoidal, with interphase interval	Rectangular	Rectangular	Same
Maximum Output Voltage (volts)		160mV±10% @500Ω	30.8V @500Ω	0.347V±5% @500Ω	Similar
Maximum Output Current (specify units)		0.32mA±10% @500Ω	61.6mA @500Ω	0.647mA±5% @500Ω	
Pulse width (μsec)		2.5-2500mS±10%	1-10000mS	3.24-1610mS	
Max. pulse frequency (Hz) [or Rate (pps)]		0.3-200Hz±10%	0.1-300Hz	0.621-308.6Hz	
Net Charge (μC per pulse)		150μC @500Ω	Unpublished	0μC @500Ω	Similar
Maximum Phase Charge		200μC@500Ω	Unpublished	190μC @500Ω	
Maximum Average Current		0.16mA@500Ω	Unpublished	0.493mA@500Ω	
Maximum Current Density		0.08mA/cm^2 @500Ω	Unpublished	1.486mA/cm^2 @500Ω	
Maximum Average Power Density		12.7μW/cm^2@500Ω	Unpublished	366E-6W/cm^2@500Ω	
Accessories		Electrode probes, Self-adhesive pads (K160081), Electrode cables	Electrode probes, DIN plug, Cotton buds	Electrode probes, Electrode cables	Same
Biocompatibility		Compliance with ISO 10993-1	Compliance with ISO 10993-1	Compliance with ISO 10993-1	Same

Table 2-

Parameters	**New Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
510(k) Number	K233667	K181062	K130065	--
Device Name	Facial Toning device	Ultra Facial Toning System	Beautiful Image Model 900 Facial Toning	--

			Device	
Model	UIC-589	/	Model 900	--
510(k) Owner	BODY TRIM INDUSTRIAL CO., LTD	Micro Current Technology, Inc.	Biosonic Technologies, LLC.	--
Intended use	The Facial Toning device is intended to stimulate the face. The device is intended for cosmetic use.	The Ultra Facial Toning System is intended to stimulate the face. The device is intended for cosmetic use.	The Beautiful Image Model 900 Facial Toning Device uses microcurrent electrical energy to stimulate facial tissues for aesthetic purposes.	Same
Type of use	Prescription Use	Prescription Use	Prescription Use	Same
Power Source(s)	100-240 VAC, 50-60 Hz	9V alkaline battery	One 6V battery	Similar
- Method of Line Current Isolation	Type BF	Type BF	N/A	Same
- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)	-- < 10μA < 50μA	-- < 10μA < 50μA	-- N/A N/A	Same
Average DC current through electrodes when device is on but no pulses are being applied (μA)	< 0.01μA	< 0.01μA	None	Same
Number of Output Modes	4	2	1	Similar
Number of Output channels:	10	2	1	Same
- Synchronous or Alternating?	Synchronous	Unpublished	N/A	Similar
- Method of Channel Isolation	Current transformer Isolation	Unpublished	N/A	Same
Regulated Current or Regulated Voltage?	Current control	Unpublished	Both	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Same
Automatic Overload Trip?	No	No	Yes	Same
Automatic No-Load Trip?	No	No	Yes	Same
Automatic Shut Off?	Yes	Yes	Yes	Same
User Override Control?	Yes	Yes	Yes	Same
Indicator On/Off	Yes	Yes	Yes	Same

Display	Status				
	Low Battery	Yes	Yes	Yes	Same
	Voltage/Current Level	Yes	Yes	Yes	Same
Timer Range (minutes)		1~ 60 minutes, 1min/step	12 or 15 minutes	None	Same
Compliance with Voluntary Standards?		AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1	Same
Compliance with 21 CFR 898?		Yes	Yes	Yes	Same
Weight (grams)		2kg	Unpublished	10lbs	Similar
Dimensions (mm) [W x H x D]		360*255*50mm	Unpublished	5.5*15.3*11.3(in.)	
Housing Materials & Construction		Panel :PMMA Middle Frame :ABS Bottom Case: Iron	Unpublished	Thermoplastic	Similar
Waveform		Pulsed, monophasic	Pulsed, monophasic	biphasic	Same
Shape		Rectangular, trapezoidal, with interphase interval	Rectangular	Rectangular	Same
Maximum Output Voltage (volts)		160mV±10% @500Ω	30.8V @500Ω	0.347V±5% @500Ω	Similar
Maximum Output Current (specify units)		0.32mA±10% @500Ω	61.6mA @500Ω	0.647mA±5% @500Ω	
Pulse width (μsec)		2.5-2500mS±10%	1-10000mS	3.24-1610mS	
Max. pulse frequency (Hz) [or Rate (pps)]		0.3-200Hz±10%	0.1-300Hz	0.621-308.6Hz	
Net Charge (μC per pulse)		150μC @500Ω	Unpublished	0μC @500Ω	Similar
Maximum Phase Charge, (μC)		200μC@500Ω	Unpublished	190μC @500Ω	Similar
Maximum Average Current, (mA)		0.16mA@500Ω	Unpublished	0.493mA@500Ω	Similar
Maximum Current Density, (mA/cm², r.m.s.)		0.08mA/cm2 @500Ω	Unpublished	0.1.486mA/cm2 @500Ω	
Maximum Average Power Density		12.7μW/cm2@500Ω	Unpublished	366E-6W/cm2@500Ω	
Accessories		Electrode probes, Self-adhesive pads (K160081), Electrode cables	Electrode probes, DIN plug, Cotton buds	Electrode probes, Electrode cables	Same
Biocompatibility		Compliance with ISO 10993-1	Compliance with ISO 10993-1	Compliance with ISO 10993-1	Same

The proposed device has the similar indication for use as the predicate device as well as comparable technical and biocompatibility properties and characteristics, and the minor differences don’t raise any additional questions for safety and effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.

5. Non-clinical Testing Summary

Bench tests were conducted to verify that the proposed device met all requirements. The test results demonstrated that the proposed device complies with the following standards:

- AAMI / ANSIES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

-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 disturbances - Requirements and tests

- IEC 60601-2-10 Edition 2.1 2016-04, Medical Electrical Equipment -- Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators.

- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)

- ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for skin sensitization,

- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation.

- IEC 62133-2 Edition1.0 2017-02， 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

6. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission, the subject device is as safe, as effective, as the legally marketed predicate device K181062, K130065.