September 9, 2024

Shenzhen Minghuangda Electronics Co., Ltd.
Guixiang Zhang
Official Applicant
Floor 6, Building A, Taixinglong Industrial Park,
Hezhou Village, Xixiang Town,Baoan District
Shenzhen, Guangdong 518100
China

Re: K241678
Trade/Device Name: TENS & EMS Stimulator (MHD-1083)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: May 31, 2024
Received: June 11, 2024

Dear Guixiang Zhang:

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,

Doe W. Kumsa -S

for Pamela Scott, MS
Assistant Director
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)*
K241678

Device Name
TENS and EMS Stimulator (MHD-1083)

Indications for Use *(Describe)*

Transcutaneous Electrical Nerve Stimulation (Program 3,4,6,7,8,9,16,17,19,20,21,22,23,24,28,29,34,36):
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.

Electrical Muscle Stimulation (Program 1,2,5,10,11,12,13,14,15,18,25,26,27,30,31,32,33,35): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K241678
Date:	May 31,2024
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Shenzhen Minghuangda Electronics Co.,LTD Floor6, Building A, Taixinglong Industrial Park, Hezhou Village, Xixiang Town, Baoan District, Shenzhen City, China.
Contact:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 602, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description:

Proprietary Name:	TENS & EMS Stimulator(Model:MHD-1083)
Common Name:	TENS & EMS
Classification Name:	Stimulator, nerve, transcutaneous, over-the-counter, Stimulator, muscle, powered, for muscle conditioning
Regulation Number:	882.5890, 890.5850
Product Code:	NUH, NGX
Device Class:	II
Review Panel:	Neurology & Physical Medicine
Device Description:	TENS & EMS Stimulator(Model:MHD-1083) is portable and DC 3.7V battery powered device, offering both transcutaneous electrical nerve stimulator (TENS) and electrical muscle stimulation (EMS) qualities in one device. TENS & EMS Stimulator has 36 operation programs, which can give certain electrical pulses through electrode adhesive pads to the suggested area of the body where the electrodes are placed. And the TENS (Program 3,4,6,7,8,9,16,17,19,20,21,22,23,24,28,29,34,36) to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve. Electrical Muscle Stimulation (EMS) (Program 1,2,5,10,11,12,13,14,15,18,25,26,27,30,31,32,33,35) to be used to stimulate healthy muscles in order to improve and facilitate muscle performance. The electronic stimulatory module has the operating elements of Switch, LCD Display screen, Screen lock key, Intensity Modification keys, Timing key, Output sockets, and USB port for battery charging. The LCD screen can display treatment remaining time, battery power,

	selected program, output port, current intensity, selected intensity and lock state. The device is equipped with accessories of electrode pads, electrode cables, a battery charger and a USB cable. The electrode cables are used to connect the pads to the device; the USB cable is used to connect the AC charger and the built-in lithium battery. All accessories, including the USB cable, electrode pads, electrode cables, and the charger can only be replaced by the specialized person. Please ask the retailer to replace it. The electrodes are interchangeable. The application area of electrode pads must be larger than $10cm^2$. The electrode pads are provided by Dong Guan Ou Kang Electronics CO., LTD. with 510(k) cleared Number K181234.
Indications for use:	Transcutaneous Electrical Nerve Stimulation (Program 3,4,6,7,8,9,16,17,19,20,21,22,23,24,28,29,34,36): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve. Electrical Muscle Stimulation (Program 1,2,5,10,11,12,13,14,15,18,25,26,27,30,31,32,33,35): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

3. Predicate Device Identification

Predicate 510(k) Number:	K190115
Marketing Clearance Date:	June 19,2019
Product Name:	MHD TENS
Manufacturer:	MingHuangDa Electronic Co.,Ltd
Predicate 510(k) Number:	K133929
Marketing Clearance Date:	November 12,2014
Product Name:	Health Expert Electronic Stimulator, Model: AST-300C and AST-300D
Manufacturer:	Shenzhen OSTO Technology Company Limited

4. Substantial Equivalence to Predicate device:

Detailed comparison data is included in "Section 9 - Substantial Equivalence Discussion" of this 510(k) submission.

Parameters		**New Device**	**Predicate Device**	**Reference Device**	**Comparison**
1.	510(k) Number:	To be assigned	K190115	K133929	--
2.	Marketing clearance date:	---	06/19/2019	11/12/2014	--
3.	Device Name	TENS & EMS Stimulator (Model:MHD-1083)	MHD TENS	Health Expert Electronic Stimulator, Model: AST-300C and AST-300D	--
4.	Manufacturer	Shenzhen Minghuangda Electronics Co.,LTD	MingHuangDa Electronic Co.,Ltd	Shenzhen OSTO Technology Company Limited	--
5.	Indications for Use	Transcutaneous Electrical Nerve Stimulation (Program 3,4,6,7,8,9,16,17,19,20,21,22,23,24,28,29,34,36):To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve. Electrical Muscle Stimulation (Program 1,2,5,10,11,12,13,14,15,18,25,26,27,30,31,32,33,35): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	Transcutaneous Electrical Nerve Stimulation (Program 2, 3, 4, 6, 8, 9): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. Powered Muscle Stimulation (Program 1, 5, 7, 10, 11, 12): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	TENS (Mode 9~25) To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve. PMS (Mode 1~8) It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.	Same

6.	Type of use	OTC	OTC	OTC	Same
7.	Power Source(s)	DC 3.7V lithium battery	DC 3.7V lithium battery	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	Same
	- Method of Line Current Isolation	Type BF	Type BF	Type BF Applied Part	Same
	- Patient Leakage Current	--	--	--	Same
	- Normal Condition (μA)	< 10μA	< 10μA	AC: 54.5μA, DC: 0.5μA	
	- Single Fault Condition (μA)	< 50μA	< 50μA	AC:120.0μA, DC: 0.6μA	
8.	Average DC current through electrodes when device is on but no pulses are being applied (μA)	< 0.01μA	< 0.01μA	< 0.01μA	Same
9.	Number of Output Modes	36	12	25	Similar Note 2
10.	Number of Output channels:	2	2	2	Same
	- Synchronous or Alternating?	Alternating	Alternating	Synchronous	Same
	- Method of Channel Isolation	Voltage transformer Isolation	Voltage transformer Isolation	Voltage Transform Isolation “BODY▼” and “ BODY▼” buttons for body channel, “ SOLE▲” and “SOLE▼” buttons for feet channel	Same
12.	Regulated Current or Regulated Voltage?	Regulated current	Regulated current	Voltage Control	Same
13.	Software/Firmware/ Microprocessor Control?	Software	Software	Yes	Same
14.	Automatic Overload Trip?	No	No	No	Same
15.	Automatic No-Load Trip?	No	No	No	Same
16.	Automatic Shut Off?	Yes	Yes	Yes	Same
17.	User Override Control?	No	Yes	Yes	Similar Note 1

18.	Indicator Display:	On/Off Status?	Yes	Yes	Yes	Same
		Low Battery?	Yes	Yes	No	Same
		Voltage/ Current Level?	No	Yes	Yes	Similar Note 1
19.	Timer Range (minutes)		0 ~ 60 minutes, 10 min/step	10 ~ 60 minutes, 10 min/step	25min	Similar Note 2
20.	Compliance with Voluntary Standards?		Yes. IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Yes. IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Yes. IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO 10993-5, ISO 10993-10	Same
21.	Compliance with 21 CFR 8988?		Yes	Yes	Yes	Same
22.	Weight (grams)		50g	110g	2Kg (Without accessories)	Similar Note 2
23.	Dimensions (mm) [W x H x D]		93.8*54*10.8mm	132.8*65.8*13.8mm	428mm x 428.8mm x 185mm	Similar Note 2
24.	Housing Materials & Construction		ABS+aluminium alloy	ABS+aluminium alloy	Main unit: ABS plastic	Same
25.	Waveform		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Same
26.	Shape		Rectangular, with interphase interval	Rectangular, with interphase interval	Rectangular, with interphase interval	Same
27.	Maximum Output Voltage (volts)		82V±20% @500Ω	78V±15% @500Ω	44V±10% @ 500Ω	Similar Note 3
			158V±20% @2kΩ	153V±15% @2kΩ	80V±10% @ 2KΩ	
			168V±20% @10kΩ	161V±15% @10kΩ	112V±10% @ 10KΩ	
28.	Maximum Output Current (specify units)		164mA±20% @500Ω	156mA±15% @500Ω	88mA±10% @ 500Ω	
			79mA±20% @2kΩ	76.5mA±15% @2kΩ	40mA±10% @ 2KΩ	
			16.8mA±20% @10kΩ	16.1mA±15% @10kΩ	11.2mA±10% @10KΩ	
29.	Pulse width (μsec)		90μs±20%	Positive phase: 78μs±10% Negative phase: 78μs±10% Interphase interval: 70μs±10%	120μs	
30.	Pulse Period (msec)		10.3~833.3ms	14.3~1000ms	129ms	
31.	Max. pulse frequency (Hz) [or Rate (pps)]		1.2~96.8Hz±20%	1~70Hz	77.3Hz	
32.	Net Charge (μC per		0μC @500Ω; Method:	0μC @500Ω; Method:	0μC @500Ω; Method:	Same

	pulse)	Balanced waveform	Balanced waveform	Balanced waveform	
33.	Maximum Phase Charge, (μC)	14.76μC @500Ω	12.17μC@500Ω	12.780μC @500Ω	Similar Note 4
34.	Maximum Average Current, (mA)	1.16mA @500Ω	0.852mA@500Ω	0.968mA @ 500Ω	
35.	Maximum Current Density, (mA/cm², r.m.s.)	0.22mA/cm^2 @500Ω (Smallest electrode area 10cm^2)	0.142mA/cm^2@500Ω (Smallest electrode area 12cm^2)	0.235mA/cm² @500Ω	
36.	Maximum Average Power Density, (mW/cm²)	14.52mW/cm^2 @500Ω (Smallest electrode area 10cm^2)	5.54mW/cm^2 @500Ω (Smallest electrode area 12cm^2)	1.38mW/cm² @500Ω	
37.	Battery charge	① The Lithium battery can be recharged through AC adaptor input. ② When charging is finished, the LCD will show full cell of battery.	① The Lithium battery can be recharged through both AC adaptor and computer USB input. ② When charging is finished, the LCD will show full cell of battery.	Not published	Similar Note 2
38.	Accessories	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Self-adhesive electrodes, electrode wires, Battery charger, USB cable, Screen stylus	Not published	Similar Note 2

Comparison in details:

Note 1:

The user override control, voltage/current level and battery charge of the proposed device are different from the primary predicate device. Considering the proposed device and predicate device adopt the same fundamental output technology and similar treatment effect. Therefore, this item is considered to be substantially equivalent. Also, the proposed device had passed AAMI / ANSI ES60601-1 and IEC 60601-2-10 tests, so these differences don't raise any new safety and effectiveness issues.

Note 2

The number of output modes, time range, weight, dimensions, appearances and accessories of the proposed device are a little different from the predicate device, depending on the design and sales requirements of the product,but these differences do not impact safety and effectiveness.

Note 3:

There are some differences on the maximum output voltage and maximum output current between the proposed device and predicate device. Based on the calculation of maximum current density, maximum average power density, these parameters don't exceed the safety limit. All deviation and the worst case have been considered in risk analysis report, and these parameters have met the requirements of IEC 60601-2-10. So these differences will not raise any new safety and effectiveness issues. Although the pulse width, pulse period and frequency of the proposed device are a little different and bring up a difference in the maximum charge per phase the difference will not alter the ability of the device from performing similar to the predicate device. The small difference of function specifications will not raise any safety or effectiveness issue.

	Note 4: Based on the calculation of maximum current density, maximum average power density, these parameters don't exceed the safety limits of 2 mA/cm^2 and 0.25 W/cm^2. All deviation and the worst case have been considered in risk analysis report, and these parameters have passed IEC 60601-2-10 test codes. So these differences will not raise any new safety and effectiveness issues. Although the parameters of the proposed device are a little different from the predicate device, but they are all compliance with IEC 60601-2-10 requirements. So, the minor difference in specification will not raise any safety or effectiveness issue.

5. Safety and Effectiveness of the device:

TENS & EMS Stimulator(Model:MHD-1083) is as safe and effective as the predicate devices cited above.

The new device has passed testing according to the safety standards:

1) ANSI AAMI ES60601-1:2005/(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)]

2) ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]

3) 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.

4) IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION 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

5) IEC 62133 Edition 2.0 2012-12, IEC 62133 Edition 2.0 2012-12 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 [Including: Corrigendum 1 (2013)]

The conclusion drawn from the safety testing is that the new device is substantially equivalent to the predicate device. Furthermore, the new device complies with the recognized standards and performs its intended tasks as well as the legally marketed predicate devices.