June 19, 2019

MingHuangDa Electronic Co., Ltd
℅ Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903, No.19 Dongbao Road
Songjiang Area
Shanghai, 201613 CN

Re: K190115
Trade/Device Name: MHD TENS
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: March 13, 2019
Received: March 21, 2019

Dear Doris Dong:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Vivek Pinto
Assistant Director, Acute Injury Team
DHT5B: Division of Neuromodulation
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190115

Device Name
MHD TENS

Indications for Use *(Describe)*

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.

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:	K190115
Date:	June 18, 2019
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	MingHuangDa Electronic 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 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris_d@126.com Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description:

Proprietary Name:	MHD TENS
Common Name:	TENS & PMS
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:	MHD TENS is portable and DC 3.7V battery powered device, offering both transcutaneous electrical nerve stimulator (TENS) and powered muscle stimulator (PMS) qualities in one device. MHD TENS has 12 operation programs, which can give certain electrical pulses through electrode adhesive pads to the suggested area of the body where the electrodes are placed. 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 screen stylus, 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. The screen stylus is used to touch and operate the display screen. 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 12cm^2. The electrode pads are provided by Shenzhen Mailuokang Technology Co., Ltd. with 510(k) cleared Number K152815.
Indications for use:	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.

3. 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**	**Same/Different**
1.	510(k) Number:	K190115	K143268	
2.	Marketing clearance date:		07/21/2015	
3.	Device Name	MHD TENS	TENS AND POWERED MUSCLE STIMULATOR	
4.	Manufacturer	MingHuangDa Electronic Co.,Ltd	Shenzhen As-Tec Technology Co., Ltd.	
5.	Intended use	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: 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. PMS: It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	Same
6.	Type of use	OTC	OTC	Same
7.	Power Source(s)	DC 3.7V lithium battery	DC 3.7V lithium battery	Same
	- Method of Line Current Isolation	Type BF	Type BF	Same
	- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)	-- < 10μA < 50μA	-- 0.1μA 0.1μA	Similar Note 1
8.	Average DC current through electrodes	< 0.01μA	< 0.01μA	Same

	when device is on but no pulses are being applied (μA)			
9.	Number of treatment programs	12	6	Similar Note 1
10.	Number of Output channels:	2	2	Same
	- Synchronous or Alternating?	Alternating	Synchronous	Different Note 1
	- Method of Channel Isolation	Voltage transformer Isolation	Voltage transformer Isolation	Same
11.	Regulated Current or Regulated Voltage?	Regulated current	Voltage control	Different Note 1
12.	Software/Firmware/Microprocessor Control?	Software	Software	Same
13.	Automatic Overload Trip?	No	No	Same
14.	Automatic No-Load Trip?	No	No	Same
15.	Automatic Shut Off?	Yes	Yes	Same
16.	User Override Control?	Yes	Yes	Same
17.	Indicator Display: On/Off Status?	Yes	Yes	Same
	Low Battery?	Yes	Yes	Same
	Voltage/ Current Level?	Yes	Yes	Same
18.	Timer Range (minutes)	10 ~ 60 minutes, 10 min/step	10 ~ 60 minutes, 10 min./step	Same
19.	Compliance with Voluntary Standards?	Yes. AAMI / ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Yes. AAMI / ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Same
20.	Compliance with 21 CFR 8988?	Yes	Yes	Same
21.	Weight (grams)	110g	170g	Similar
22.	Dimensions (mm) [W x H x D]	132.8*65.8*13.8mm	93*50*9mm	Similar
23.	Housing Materials & Construction	ABS+aluminium alloy	ABS	Similar

24.	Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Same
25.	Shape	Rectangular, with interphase interval	Rectangular, with interphase interval	Same
26.	Maximum Output Voltage (±15%)	Program 1: 51.2V@500Ω 94V@2kΩ 156V@10kΩ Program 2: 48V@500Ω 39.2V@2kΩ 49.6V@10kΩ Program 3: 69.6V@500Ω 98V@2kΩ 98V@10kΩ Program 4: 57.6V@500Ω 76V@2kΩ 124V@10kΩ Program 5: 49.6V@500Ω 74V@2kΩ 134V@10kΩ Program 6: 57V@500Ω 82V@2kΩ 138V@10kΩ Program 7: 51.2V@500Ω 100V@2kΩ 154V@10kΩ Program 8: 64V@500Ω 104V@2kΩ 134V@10kΩ Program 9:	Program 1: 35.5V@500Ω 52.5V@2kΩ 68.5V@10kΩ Program 3: 53.5V@500Ω 67V@2kΩ 68V@10kΩ Program 3: 53.5V@500Ω 67V@2kΩ 68V@10kΩ Program 1: 35.5V@500Ω 52.5V@2kΩ 68.5V@10kΩ Program 2: 30V@500Ω 52.5V@2kΩ 64.5V@10kΩ Program 1: 35.5V@500Ω 52.5V@2kΩ 68.5V@10kΩ Program 1: 35.5V@500Ω 52.5V@2kΩ 68.5V@10kΩ Program 6: 33V@500Ω 55.5V@2kΩ 67.5V@10kΩ Program 6:	Similar Note 2

		63.2V@500Ω 94V@2kΩ 128V@10kΩ Program 10: 78V@500Ω 150V@2kΩ 168V@10kΩ Program 11: 51.2V@500Ω 98V@2kΩ 154V@10kΩ Program 12: 76V@500Ω 152V@2kΩ 154V@10kΩ	33V@500Ω 55.5V@2kΩ 67.5V@10kΩ Program 1: 35.5V@500Ω 52.5V@2kΩ 68.5V@10kΩ Program 1: 35.5V@500Ω 52.5V@2kΩ 68.5V@10kΩ Program 1: 35.5V@500Ω 52.5V@2kΩ 68.5V@10kΩ	
27.	Maximum Output Current (±15%)	Program 1: 102.4mA@500Ω 47mA@2kΩ 15.6mA@10kΩ Program 2: 96mA@500Ω 19.6mA@2kΩ 4.96mA@10kΩ Program 3: 139.2mA@500Ω 49mA@2kΩ 9.8mA@10kΩ Program 4: 115.2mA@500Ω 38mA@2kΩ 12.4mA@10kΩ Program 5: 99.2mA@500Ω 37mA@2kΩ 13.4mA@10kΩ Program 6: 114mA@500Ω	Program 1: 71mA@500Ω 26.3mA@2kΩ 6.9mA@10kΩ Program 3: 107mA@500Ω 33.5mA@2kΩ 6.8mA@10kΩ Program 3: 107mA@500Ω 33.5mA@2kΩ 6.8mA@10kΩ Program 1: 71mA@500Ω 26.3mA@2kΩ 6.9mA@10kΩ Program 2: 60mA@500Ω 26.3mA@2kΩ 6.5mA@10kΩ Program 1: 71mA@500Ω	Similar Note 2

		41mA@2kΩ 13.8mA@10kΩ Program 7: 102.4mA@500Ω 50mA@2kΩ 15.4mA@10kΩ Program 8: 128mA@500Ω 52mA@2kΩ 13.4mA@10kΩ Program 9: 126.4mA@500Ω 47mA@2kΩ 12.8mA@10kΩ Program 10: 156mA@500Ω 75mA@2kΩ 16.8mA@10kΩ Program 11: 102.4mA@500Ω 49mA@2kΩ 15.4mA@10kΩ Program 12: 152mA@500Ω 76mA@2kΩ 15.4mA@10kΩ	26.3mA@2kΩ 6.9mA@10kΩ Program 1: 71mA@500Ω 26.3mA@2kΩ 6.9mA@10kΩ Program 6: 66mA@500Ω 27.8mA@2kΩ 6.75mA@10kΩ Program 6: 66mA@500Ω 27.8mA@2kΩ 6.75mA@10kΩ Program 1: 71mA@500Ω 26.3mA@2kΩ 6.9mA@10kΩ Program 1: 71mA@500Ω 26.3mA@2kΩ 6.9mA@10kΩ Program 1: 71mA@500Ω 26.3mA@2kΩ 6.9mA@10kΩ	
28.	Pulse width (μsec)	Positive phase: 78μs±10% Negative phase: 78μs±10% Interphase interval: 70μs±10%	Positive phase: 225μs Negative phase: 225μs Interphase interval: 225μs	Similar Note 2
29.	Max. pulse frequency (Hz) [±10%]	Program 1: 46Hz Program 2: 3.3-31Hz Program 3: 1.1Hz Program 4: 65Hz Program 5: 70Hz Program 6: 2.8-65Hz Program 7: 45-65Hz Program 8: 3.1-52.6Hz	Program 1: 47.6Hz Program 3: 1.62Hz Program 3: 1.62Hz Program 1: 47.6Hz Program 2: 3.2~47.6Hz Program 1: 47.6Hz Program 1: 47.6Hz Program 6: 47.6Hz	

		Program 9: 1.8-65Hz Program 10: 1-46Hz Program 11: 46Hz Program 12: 1-46Hz	Program 6: 47.6Hz Program 1: 47.6Hz Program 1: 47.6Hz Program 1: 47.6Hz	
30.	Net Charge (μC per pulse)	0μC @500Ω; Method: Balanced waveform	0μC @500Ω; Method: Balanced waveform	Same
31.	Maximum Phase Charge, (μC)	24.3μC @500Ω	48μC @500Ω	Similar Note 3
32.	Maximum Average Current, (mA)	0.852mA@500Ω	2.72mA	Similar Note 4
33.	Maximum Current Density, (mA/cm², r.m.s.)	0.142mA/cm^2 @500Ω(Smallest electrode area 12cm^2)	1.36mA/cm^2 (Smallest electrode area 4cm^2)	
34.	Maximum Average Power Density, (mW/cm²)	5.54mW/cm^2 @500Ω (Smallest electrode area 12cm^2)	36.4mW/cm^2 (Smallest electrode area 4cm^2)	
35.	Battery charge	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.	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.	Same
36.	Accessories	Self-adhesive electrodes, electrode wires, Battery charger, USB cable, Screen stylus	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Similar Note 5

Differences between proposed device and predicate device:

Note 1:

The Patient Leakage Current and Regulated Current or Regulated Voltage between the proposed device and the predicate device has slight difference. But both of them have passed AAMI / ANSI ES 60601-1 test code, so these differences won't raise any new safety and effectiveness issues.

The proposed device has more treatment programs than the predicate device. The output two channels of the proposed device are alternating while the predicate device are synchronous. Because the stimulus delivery between proposed device and predicate device which adopt the same fundamental output technology including same waveform and similar modes will offer the similar treatment effect. Therefore, these items are considered to be substantially equivalent. Also, the proposed device have passed AAMI / ANSI ES 60601-1 and IEC 60601-2-10 test codes, so these differences won't raise any new safety and effectiveness issues.

Note 2:

There are some differences on the maximum output voltage, maximum output current, pulse width and frequency between proposed device and predicate device. Through calculation and measurement, these parameters meet the requirement of AAMI/ANSI ES 60601-1 and IEC 60601-2-10 test codes. Specially, the

physiological effectiveness of stimulation is primarily dependent on delivered charge. Therefore these differences won't raise any new safety and effectiveness issues.

Note 3:

The maximum phase charge of the proposed device is less than the predicate device, but the cleared device K121719, which is the predicate device of K143268, has the maximum phase charge of 16.8μC@500Ω. The value of the proposed device is between these two values, therefore this difference won't raise any new safety and effectiveness issues.

Note 4:

The maximum average current, maximum current density and maximum power density have some differences between proposed device and predicate device. Per IEC 60601-2-10 test code, the maximum current density of the proposed device is less than 2mA/cm². Meanwhile, the maximum average power density of the proposed device is less than 0.25W/cm². Therefore these differences won't raise any new safety and effectiveness issues.

Note5:

The proposed device has a screen stylus while the predicate device doesn't have. The proposed device has a touchable display screen and a lock screen button. The screen stylus is to click the display and the lock button is to prevent wrong touch. This function doesn't affect output parameters or operation, so this difference don't raise any safety and effectiveness issues.

4. Safety and Effectiveness of the device:

MHD TENS is 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 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD);

2) 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;

3) ANSI AAMI IEC 60601-1-2:2014, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests;

4) 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)]

5) IEC 60601-1-11 Edition 2.0 2015-01, 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 . (General II (ES/EMC))

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.