October 2, 2017

Shenzhen Dongdixin Technology Co., Ltd.
Siping Yuan
R.A. Specialist
No. 3 Building Xilibaimang Xusheng Industrial Estate
Nanshan
Shenzhen, 518108 CN

Re: K171978
Trade/Device Name: Combo Stimulator MT9000, Combo Stimulator LT7102, TENS Stimulator InTENSity 10
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, LIH
Dated: June 15, 2017
Received: July 5, 2017

Dear Siping Yuan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171978

Device Name
Combo Stimulator MT9000, Combo Stimulator LT7102, TENS Stimulator InTENSity 10

Indications for Use *(Describe)*

Combo Stimulator MT9000
For TENS/IF/MIC mode
1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. Post surgical pain

For EMS mode
1. Relaxation of muscle spasm.
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of muscles to prevent venous thrombosis

Combo Stimulator LT7102
For TENS/IF/MIC mode
1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. Post surgical pain

For EMS/RUSS mode
1. Relaxation of muscle spasm.
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of muscles to prevent venous thrombosis

TENS Stimulator InTENSity 10
1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. Post surgical pain

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 section 21 CFR 807.92

Date of Submission: 06/15/2017

Submitter's Name: Shenzhen Dongdixin Technology Co., Ltd

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Contact: Siping Yuan

1. Proposed Device:

1)

Trade Name:	Combo Stimulator MT9000 Combo Stimulator LT7102 TENS Stimulator Intensity 10
Classification Name:	Stimulator, Muscle, Powered
Regulation Number:	890.5850
Product Code:	IPF
Device Class:	II

2)

Trade Name:	Combo Stimulator MT9000 Combo Stimulator LT7102
Classification Name:	Stimulator, Nerve, Transcutaneous. For pain relief
Regulation Number:	882.5890
Product Code:	GZJ
Device Class:	II

3)

Trade Name:	Combo Stimulator MT9000 Combo Stimulator LT7102
Classification Name:	Interferential current therapy
Regulation Number:	Unclassified
Product Code:	LIH
Device Class:	II

2. Predicate Device:

Legally Marketed Device:	MT9000 Series Electro-Stimulator
510(k) Number:	K093138
Manufacturer:	Shenzhen Dondixin Technology Co., Ltd.

Legally Marketed Device:	Sonicator® Plus 940, ME940
510(k) Number:	K071137
Manufacturer:	Mettler Electronics Corp.

3. Description of Proposed Device:

MT9000, LT7102 and Intensity 10 are Transcutaneous Electrical Nerve Stimulator and muscle stimulator for pain relief and/or Electrical Muscle Stimulator. The stimulator sends gentle electrical current to underlying nerves and muscle group via electrode applied on the skin. The parameters of units are controlled by the press buttons. Its intensity level is adjustable according

to the needs of patients.

The 3 models MT9000, LT7102 and Intensity 10 have similar housing with a viewable LCD display, an accessible keypad, and accessible battery storage compartment. The LCD is located on the upper half of the rectangular face of the device, above the keypad. The LCD is used to display system information to the user.

4. Description of All Device Modification(s)

The Combo Stimulator MT9000 only changes the energy type and added the adapter power supply. Compared with the existing device (MT9000), they have the same control mechanism, IFU, operating principle, performance specification, dimensional specifications, materials and software. The new change part have been evaluated and passed the requirement based on IEC60601-1, IEC60601-1-2 and IEC60601-2-10.

The Combo Stimulator LT7102 change the 9-volt battery to the recharge Lithium battery, add the electrode accessories like as different part electrode belt and make it more convenient for the user. Meanwhile, we added the RUSSIAN electrical stimulation mode that together with the TENS, EMS, IF and MICROCURRENT. Compared with the existing device (MT9000), they have the same control mechanism, IFU, operating principle, materials and performance specification. And this modification does not affect the intended use of the device or alter the fundamental scientific technology of the device. The new change part have been evaluated and passed the requirement based on IEC60601-1, IEC60601-1-2 and IEC60601-2-10.

Compared with the existing device (MT9001), The TENS Stimulator Intensity 10 only has TENS mode and the following parts have changed:

1) Changes the energy type and added the adapter power supply.
2) Change the dimensional specification.
3) Change the LCD UI and make it more convenient for the user.

And these changes have been evaluated and passed the requirement based on IEC60601-1, IEC60601-1-2 and IEC60601-2-10.

5. Proposed Device Intended for Use Statement:

Device Name: Combo Stimulator MT9000, Combo Stimulator LT7102, TENS Stimulator Intensity 10

Indications for Use:

Combo Stimulator MT9000

For TENS/IF/MIC mode

1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. Post surgical pain

For EMS mode

1. Relaxation of muscle spasm.
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Combo Stimulator LT7102

For TENS/IF/MIC mode

1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. Post surgical pain

For EMS/RUSS mode

1. Relaxation of muscle spasm.
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of muscles to prevent venous thrombosis

TENS Stimulator Intensity 10

1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain
3. Post surgical pain

6. Technological Characteristics and Substantial Equivalence

		New device	New device	New device	Predicate device	Predicate device	Discussion
1	510K#	To be assigned	To be assigned	To be assigned	K093138	K071137	N/A
2	Device Name	Combo Stimulator LT7102	Combo Stimulator MT9000	TENS Stimulator Intensity 10	MT9000 Combo TENS/EMS/IF/MIC Stimulator	Sonicator Plus940	N/A
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd.				Mettler Electronics	N/A
4	Intended for use	**Combo Stimulator MT9000** For TENS/IF/MIC mode 1. Symptomatic relief of chronic intractable pain 2. Post traumatic pain 3. Post surgical pain For EMS mode 1. Relaxation of muscle spasm. 2. Increase of local blood flow circulation 3. Prevention or retardation of disuse atrophy 4. Muscle re-education 5. Maintaining or increasing range of motion. 6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis **Combo Stimulator LT7102** For TENS/IF/MIC mode 1. Symptomatic relief of chronic intractable pain 2. Post traumatic pain 3. Post surgical pain			For TENS/IF/MIC mode 1. Symptomatic relief of chronic intractable pain 2. Post traumatic pain 3. post surgical pain For EMS mode 1. Relaxation of muscle spasm. 2. Increase of local blood flow circulation 3. Prevention or retardation of disuse atrophy 4. Muscle re-education 5. Maintaining or increasing range of motion.	4-Pole Interferential, 2-Pole Interferential, TENS and Microcurrent waveforms 1. Symptomatic relief of chronic intractable pain 2. Post-traumatic pain 3. Post-surgical pain EMS, TENS, Hi Volt and Russian waveforms l. Relaxation of muscle spasms 2. Increase local blood circulation 3. Prevention or retardation of disuse atrophy 4. Muscle re-education	Same

		For EMS/RUSS mode 1. Relaxation of muscle spasm. 2. Increase of local blood flow circulation 3. Prevention or retardation of disuse atrophy 4. Muscle re-education 5. Maintaining or increasing range of motion. 6. Immediate post-surgical stimulation of muscles to prevent venous thrombosis **TENS Stimulator Intensity 10** 1. Symptomatic relief of chronic intractable pain 2. Post traumatic pain 3. Post surgical pain			6. Immediate post-surgical stimulation of muscles to prevent venous thrombosis	5. Maintaining or increasing range of motion 6. Immediate post surgical stimulation of calf muscles to prevent venous thrombosis	
5	Power Source	3.7V Li-ion Battery Charger output: 5.0V DC, 300mA	9V Battery Adapter Output: 9V DC 0.8A	9V Battery Adapter Output: 9V DC 0.8A	9V Battery	AC Line	Different, but they all comply with IEC 60601-1 requirements.
	Method of Line current isolation	N/A	N/A	N/A	Battery Supply N/A	Reinforced insulation	
	- Patient Leakage Current -Normal condition -Single fault condition	 5 uA 5 uA	 4 uA 4 uA	 1 uA 9 uA	 0.61uA 0.68uA	 >50uA >50uA	
6	Number of Output Modes	5	4	1	MT9000 4 MT9001 1 MT9002 1 MT9003 1 MT9004 1	8	Different, the number of output mode is the feature of device, doesn't affect the safety and effectiveness
7	Number of Output Channels	2	2	2	2	4	Different, the number of output channels is the feature of device, doesn't

							affect the safety and effectiveness
	- Synchronous or Alternating?	Synchronous and Alternating	Synchronous and Alternating	Synchronous	Synchronous and Alternating	Synchronous and Alternating	Similar
	- Method of Channel Isolation?	By enclosure	By enclosure	By enclosure	By enclosure	By transformer	Different, but they all comply with IEC 60601-1 requirements.
8	Constant Current? Constant Voltage?	Yes No	Yes No	Yes No	Yes No	Yes No	Same
9	Software/Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Same
10	Automatic Overload Trip? Automatic Over Current Trip?	Yes Yes	Yes Yes	Yes Yes	Yes Yes	Yes Yes	Same
11	Automatic No Load Trip?	Yes	Yes	Yes	Yes	Yes	Same
12	Automatic Shut off?	Yes	Yes	Yes	Yes	Yes	Same
13	Patient Override Control?	No	No	No	No	No	Same
14	Indicator Display						
	-On/Off Status?	Yes	Yes	Yes	Yes	Yes	Same
	-Voltage/Current Level?	Yes	Yes	Yes	Yes	Yes	Same
	-Low Battery?	Yes	Yes	Yes	Yes	N/A	Same
15	Waveform TENS EMS Interferential Microcurrent Russian	 Biphasic Biphasic Biphasic Monophasic Biphasic	 Biphasic Biphasic Biphasic Monophasic N/A	 Biphasic N/A N/A N/A N/A	 Biphasic Biphasic Biphasic Monophasic N/A	 Biphasic Biphasic Biphasic Monophasic or Biphasic	Similar

						Biphasic	
16	Shape TENS EMS Interferential Microcurrent Russian	 Square Square Square Square Square	 Square Square Square Square N/A	 Square N/A N/A N/A N/A	 Square Square Square Square N/A	 Square Sinusidal Sinusidal Square Gated Sinusoidal	Same with unmodified device MT9000, different from Sonicator Plus940. The shape is the feature of device, doesn't affect the safety and effectiveness
17	Max Output Voltage (V) ±20%						
	500Ω TENS EMS Interferential Microcurrent Russian	 50 50 15.75 0.4 15.75	 48 48 17.5 0.36 N/A	 52.5 N/A N/A N/A N/A	 48 48 17.5 0.36 N/A	 50 49 49 0.38 50	Similar with unmodified device MT9000, different from Sonicator Plus940, they all comply with IEC 60601-2-10.
18	Max Output Current (mA) ±20%						
	500Ω TENS EMS Interferential Microcurrent Russian	 100 100 31.5 0.8 31.5	 96 96 35 0.76 N/A	 105 N/A N/A N/A N/A	 96 96 35 0.76 N/A	 100 98 98 0.76 100	Similar with unmodified device MT9000, different from Sonicator Plus940, they all comply with IEC 60601-2-10.
19	Pulse Width Range TENS EMS Interferential Microcurrent Russian	 50-400us 200~400us 100/200/400us 2-200ms 400us	 50-300us 50-300us 125us 2-200ms N/A	 100us~260us N/A N/A N/A N/A	 50-300us 50-300us 125us 2-200ms N/A	 50-300us 500,250,200us 500,250,200us 1.25ms-1.67s 400us	Similar with unmodified device MT9000, different from Sonicator Plus940, they all comply with IEC 60601-2-10.
20	Frequency TENS EMS Interferential	 1~150Hz 1~100Hz 2.5K,5K,10K Hz	 0.5-150Hz 1-150Hz 4kHz	 50~150Hz N/A N/A	 0.5-150Hz 1-150Hz 4kHz	 0.5-250Hz 2kHz,4kHz,5kHz 2kHz,4kHz,5kHz	

	Microcurrent Russian	1-150Hz 2.5kHz	1-150Hz N/A	N/A N/A	1-150Hz N/A	0.3-400Hz 2.5kHz	
21	Beat Frequency Interferential	1-200Hz	1-150Hz	N/A	1-150Hz	1-250Hz	
22	Timer Range (minutes)	5-90 minutes	0-60 minutes	15-60 minutes	0-60 minutes	0-60 minutes	Different, the treatment time doesn't affect the safety and effectiveness
23	Compliance with Voluntary Standards?	IEC60601-1, IEC60601-1-2, IEC60601-2-10	IEC60601-1, IEC60601-1-2, IEC60601-2-10	IEC60601-1, IEC60601-1-2, IEC60601-2-10	IEC60601-1, IEC60601-1-2, IEC60601-2-10, MDD93/42/EEC, Annex Ⅱ	IEC60601-1, IEC60601-1-2, IEC60601-2-10, MDD93/42/EEC, Annex Ⅱ	Similar
24	Compliance with 21 CFR 898?	Yes	Yes	Yes	Yes	Yes	Same
25	Weight (lbs.)	0.28	0.28	0.28	0.28	11	Different, the different weight and dimension doesn't affect the safety and effectiveness.
26	Dimensions (in.) H x W x L	4.6x2.36x0.9	4.5x2.55x0.9	4.5x2.55x0.9	4.5x2.55x0.9	4.9x13.6x10.5	
27	Housing Materials & Construction	Enclosure: ABS	Enclosure: ABS	Enclosure: ABS	Enclosure: ABS	Metal Casing	Different, but they all comply with IEC 60601-1 requirements.

7. Performance Date:

The following performance data are provided in support of the substantial equivalence determination:

6.1 Biocompatibility testing

Compared with unmodified device, the new product MT9000 and Intensity 10 has the same accessories which has been evaluated based on the ISO10993 standard and submits to FDA (k093138).

The new product LT7102 added the electrode accessories like as different part electrode belt previously had been submitted with Shenzhen Dongdixin Technology Co., Ltd (k141076) which has been evaluated based on the ISO10993 standard and submit to FDA.

6.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the LT2061. The system complies with the IEC 60601-1 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

6.3 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern. IEC 62304 was followed.

8. Conclusions:

The LT7102, MT9000 and Intensity 10 have the same intended use and technological characteristics as the predicate device of Sonicator Plus 940, Model ME940 device and MT9000 Combo TENS/EMS/IF/MIC Stimulator. Moreover, bench testing and safety report supplied in this submission demonstrates that the difference in the submitted models could maintain the same safety and effectiveness as that of predicate device. In the other words, those engineering difference do not affect the intended use or alter the fundamental scientific technology of the device. Thus, the LT7102, MT9000 and Intensity 10 are substantially equivalent to the predicate device.