June 7, 2018

Shenzhen Roundwhale Technology Co., Ltd.
Kevin Zhang
General Manager
No. 615, Building C of Sanlian Industrial Zone, Shiyan, Baoan District
Shenzhen, GuangDong, CN 518108

Re: K180956
Trade/Device Name: Electrical Stimulator - Model R-C1 TENS and EMS stimulator, Model R-E1 EMS stimulator, Model R-T1 TENS Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: February 9, 2018
Received: April 12, 2018

Dear Kevin 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 (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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180956

Device Name
Electrical Stimulator - Model R-C1 TENS and EMS stimulator, Model R-E1 EMS stimulator, Model R-T1 TENS Stimulator

Indications for Use *(Describe)*

R-C1 TENS and EMS Stimulator

TENS: This mode is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

EMS: This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

R-E1 EMS Stimulator

This device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

R-T1 TENS Stimulator

This device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

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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Sponsor: Shenzhen Roundwhale Technology Co., Ltd
File No: RW-Stimulator A-FDA-8
Date: Jun. 6, 2018

510(k) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92.

The assigned 510(k) number is: K180956

1. Information of Submitter and Correspondent

Submitter's information:

Company Name:	Shenzhen Roundwhale Technology Co., Ltd
Street Address:	No. 615, Building C of Sanlian Industrial Zone, Shiyan, Baoan District
City:	Shenzhen
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Contact Person:	Kevin Zhang
Contact Title:	General Manager
Contact Email:	info@yjing.net

Submission correspondent's information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

Address: Room 2012#, Gebu commercial building, Hongxing community, Songgang street, Baoan district, Shenzhen 518000, China

Contact Person: Reanny Wang; E-mail: reanny@reanny.com

2. Device Information

a) **Trade Name:** R-C1, TENS and EMS Stimulator

Common Name: Electro-Stimulator or Electrical Stimulator

Classification Name: Stimulator, Muscle, Powered, for muscle conditioning per 21 CFR § 890.5850;
Transcutaneous Electrical Nerve Stimulator for Pain Relief;
Stimulator, Nerve, Transcutaneous, Over-the-Counter per 21 CFR § 882.5890

Device Class: Class II

Product Code: NUH, NGX

b) Trade Name: R-E1, EMS Stimulator

Common Name: Powered Muscle Stimulator, OTC

Classification Name: Stimulator, Muscle, Powered, for muscle conditioning per 21 CFR § 890.5850;

Device Class: Class II

Product Code: NGX

c) Trade Name: R-T1, TENS Stimulator

Common Name: TENS or TENS Device

Classification Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief;
Stimulator, Nerve, Transcutaneous, Over-the-Counter per 21 CFR § 882.5890

Device Class: Class II

Product Code: NUH

3. Identification of Predicate Device(s)

Manufacturer	Shenzhen Dongdixin Technology Co., Ltd
Legally Marketed Device	MT9001, LT3060
510 (K) Number	K130802

4. Description of Device

The RW Series A Electrical Stimulators, which includes models R-C1 TENS and EMS stimulator, R-E1 EMS stimulator and R-T1 TENS stimulator, 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 electrodes 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 device unit of R-C1 was portable device, battery powered (6.0V DC) multi-function device offering both Transcutaneous Electrical Nerve Stimulator(TENS) and Powered Muscle Stimulator（EMS）qualities in one device.

The electrode size is 50*50mm, the manufacturer is Top-Rank Health care Equipment Co., Ltd. The electrode is OTC use and cleared with 510(K), the cleared number is K132588. It has been evaluated and tested according to ISO 10993-1/-5 and -10 standards.

The three models of R-C1, R-E1 and R-T1 have the same appearance, structure, display, electrical principle and CDF, the main differences are software and color. The R-C1 have TENS mode (18 programs), EMS mode (15 programs). The R-E1 only have EMS mode (15 programs) and R-T1 only have TENS mode (18 programs). The R-C1 was combination the function of R-E1 and R-T1.

5. Intended Use

R-C1, TENS and EMS Stimulator

For TENS mode

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

For EMS mode

To be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

R-E1, EMS Stimulator

To be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

R-T1, TENS Stimulator

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

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6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

6.1 Non-clinical testing

A series of safety and performance tests were conducted on the subject device, RW series A Electrical stimulators (Model R-C1 TENS and EMS stimulator, Model R-E1 EMS stimulator and model R-T1 TENS Stimulator).

- Shelf life
- Software validation
- Electromagnetic compatibility and electrical safety
- Function test

All the test results demonstrate RW series A Electrical stimulators (Model R-C1 TENS and EMS stimulator, Model R-E1 EMS stimulator and model R-T1 TENS Stimulator) meets the requirements of its pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate devices.

6.2 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

7. Performance Summary

The devices conform to applicable standards as follow table:

Item	Description	FDA recognized consensus standards	Justification
Safety	IEC 60601-1:2005+ A1:2012	Yes	Conform
EMC	IEC 60601-1-2:2014	Yes	Conform
Home healthcare environment	IEC 60601-1-11:2015	Yes	Conform
Performance	IEC 60601-2-10:2012 +A1:2016	Yes	Conform
Software	IEC 62304:2006	Yes	Conform
Usability	IEC 62366-1:2015		
Risk management	ISO 14971:2007	Yes	Conform

8. Comparison for Predicate Device & Subject Device

The RW series A Electrical stimulators (Model R-C1 TENS and EMS stimulator, Model R-E1 EMS stimulator and model R-T1 TENS Stimulator) submitted in this 510(k) file is substantially equivalent in intended use, design, technology/ principles of operation, materials and performance to the cleared OTC Electrical stimulator models MT9001, LT3060 (K130802). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Comparison item	New device			Predicate device		Substantial equivalence determination
	R-C1TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	MT9001	LT3060	
510K#	Pending			K130802		N/A
Manufacturer	Shenzhen Roundwhale Technology Co., Ltd.			Shenzhen Dongdixin Technology Co., Ltd		N/A
Intended use	For TENS: This mode is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. For EMS: This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.	This device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.	This device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.	For TENS: This mode is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. For EMS: This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.	The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.	Same

Comparison item		New device			Predicate device		Substantial equivalence determination
		R-C1TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	MT9001	LT3060	
Prescription or OTC		OTC			OTC		Same
FDA product code		NUH, NGX	NGX	NUH	NUH, NGX	NUH	Same
Basic technological characteristics							
Power source		Battery powered, d.c. 6.0V, 4 X AAA batteries			Battery powered, d.c. 9.0V, one 6F22 battery		Different but does not adversely impact safety and effectiveness of subject device
User interface		By LCD display			By LCD display		Same
Output channel		Two channels			Two channels		Same
Number of output models		TENS and EMS	EMS	TENS	TENS and EMS	TENS	Same
Number of treatment programs		For TENS: 18 For EMS: 15	15	18	For TENS: 4; For EMS: 3	?	N/A
Number of output channels	Synchronous or Alternating?	Alternating			Alternating		Same
Number of output channels		2			2		Same
Method of channel isolation		By electrical circuit and software			By electrical circuit and software		Same
Constant Current or Constant Voltage?		Constant current			Constant current		Same

Comparison item		New device			Predicate device		Substantial equivalence determination
		R-C1TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	MT9001	LT3060	
Constant Current or Constant Voltage?		Constant current			Constant current		Same
Waveform		Biphasic square			Biphasic square		Same
Software/Firmware/ Microprocessor Control?		Yes			Yes		Same
Automatic overload trip?		Yes			Yes		Same
Automatic Over Current Trip?		Yes			Yes		Same
Automatic No Load Trip?		Yes			Yes		Same
Automatic shut off?		Yes			Yes		Same
Patient Override Control?		Yes			Yes		Same
Indication function	On/off status?	Yes			Yes		Same
	Low battery?	Yes			Yes		Same
	Voltage/ current level?	Yes			Yes		Same
Time range (min)		Nonadjustable 28, 30 and 32 minutes			1-60 minutes		Different but does not adversely impact safety and effectiveness of subject device

Comparison item		New device			Predicate device		Substantial equivalence determination
		R-C1TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	MT9001	LT3060	
Patient Leakage Current	- Normal condition (uA)	11.4 uA	11.4 uA	11.4 uA	0.61uA		
	- Single fault condition (uA)	9.6uA	9.6uA	9.6uA	0.68uA		
Average DC current through electrodes when device is on but no pulses are being applied (uA)		TENS: 0 EMS: 0 No output no pulse applied	TENS: N/A EMS: 0 No output no pulse applied	TENS: 0 EMS: N/A No output no pulse applied	TENS: 0 EMS: 0 No output no pulse applied		Same
Housing materials construction		Plastic (ABS) enclosure			Plastic (ABS) enclosure		Same
Treatment area		For TENS mode: shoulder, waist, back, neck, upper extremities(arm), Lower extremities (leg); For EMS: Any area (Except those treatment area which been described in the user manual can not use)	Any area (Except those treatment area which been described in the user manual can not use)	Shoulder, waist, back, neck, upper extremities(arm) , Lower extremities (leg);	For TENS mode: shoulder, waist, back, neck, upper extremities(arm), Lower extremities (leg); For EMS: Any area (Except those treatment area which been described in the user manual can not use)		Same

Comparison item		New device			Predicate device		Substantial equivalence determination
		R-C1TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	MT9001	LT3060	
List of applied part material(s)		Electrode – silica gel			Electrode – silica gel		Same
Compliance with 21 CFR 898？		Yes			Yes		Same
Classification	Type of protection against electric shock	Internally powered equipment			Internally powered equipment		Same
	Degree of protection against electric shock	Type BF applied part			Type BF applied part		Same
	Device Class	Class II			Class II		Same
Compliance with Voluntary Standards?	Mechanical Safety	Compliant with requirements of IEC 60601-1, IEC 60601-2-10 safety standards					Same
	Electrical Safety	Compliant with requirements of IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2 safety standards					Same
	Energy delivered	The delivered energy is limited according to requirements of collateral IEC 60601-2-10 safety standards					Same
	Other	Compliant with requirements of IEC 60601-11 safety standard					Same
Applied part		Electrode pad			Electrode pad		Same
Weight (lbs., oz.)		0.243			0.28		Slightly different but does not impact safety and effectiveness of subject device

Comparison item		New device			Predicate device		Substantial equivalence determination
		R-C1TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	MT9001	LT3060	
Dimensions(in.) [W × H × D] For unit		4.82x2.78x1.08			4.5x2.55x0.9		Slightly different but does not impact safety and effectiveness of subject device
Operating temperature and humidity		5℃~40℃; 15%RH~93%RH;			Unknowable		Slightly different but does not impact safety and effectiveness of subject device
Storage temperature and humidity		-10℃~55℃; 10%RH~90%RH;			Unknowable		
Output Specifications							
Waveform	TENS mode	Biphasic	N/A	Biphasic	Biphasic		Same
	EMS mode	Biphasic	Biphasic	N/A	Biphasic		Same
Shape	TENS mode	Square	N/A	Square	Square		Same
	EMS mode	Square	Square	N/A	Square		Same
Maximum output voltage (Vpp)	@500Ω	30	30	30	48	48	Different but does not adversely impact safety and effectiveness of subject device
	@2KΩ	108	108	108	100	114	
	@10KΩ	108	108	108	105	115	
Max Output Current (mA)	@500Ω	60	60	60	96		Different but does not adversely impact safety and effectiveness of subject device
	@2KΩ	54	54	54	50	57	
	@10KΩ	10.8	10.8	10.8	10.5	11.5	

Comparison item		New device			Predicate device		Substantial equivalence determination
		R-C1TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	MT9001	LT3060	
Pulse Width Range(uS)		100-380uS	200-380uS	100-330uS	50-300uS		Different but does not adversely impact safety and effectiveness of subject device
Frequency (Hz)		1-125Hz	1-110Hz	2-125Hz	1-150Hz		
For multi-program waveforms only	Symmetrical phases?	Yes	Yes	Yes	Yes		Same
	Phase Duration	100-380uS	200-380uS	100-330uS	50-300uS		Different but does not adversely impact safety and effectiveness of subject device
Net Charge per pulse cycle (uC, 500Ω)		0	0	0	0		Same
Maximum Phase Charge (uC, 500Ω)		22.8	22.8	19.8	0.0288		Different but does not adversely impact safety and effectiveness of subject device
Maximum Current Density (mA/cm^2, 500Ω, r.m.s)		2.4	2.4	2.4	1.15		
Max. average current (average absolute value, mA)		0.675	0.675	0.617	4.32		
Maximum Power Density (W/cm^2, 500Ω, r.m.s)		0.23	0.072	0.23	0.373		

Comparison item		New device			Predicate device		Substantial equivalence determination
		R-C1TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	MT9001	LT3060	
Burst mode (i.e. pulse trains)	Pulses per burst	25	N/A	25	7	N/A	Different but does not adversely impact safety and effectiveness of subject device
	Bursts per second (Hz)	2	N/A	2	0.5, 0.7,1,2,3,4, 5	N/A	
	Burst duration	250ms	N/A	250ms	70ms	N/A	
	Duty cycle	500ms	N/A	500ms	35ms/ 350ms	N/A	
On time (s)		0.5-12	N/A	0.5-12	N/A	1-30	Similar and does not impact safety and effectiveness of subject device
OFF time (s)		0.5-1	N/A	0.5-1	N/A	1-60	
Electrode area (cm^2)		25	25	25	25		Same

Similarity and Difference

The RW series A Electrical stimulators (Model R-C1 TENS and EMS stimulator, Model R-E1 EMS stimulator and model R-T1 TENS Stimulator) has been compared with “OTC electrical stimulator Models MT9001, LT3060”. The subject device has same intended use and principle of operation, similar technological characteristics as that predicate device. Although there are several specifications that are different between two devices, the comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore, the difference between the subject device and the predicate device did not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate devices in safety and performance claims.

9. Conclusions

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that the RW series A Electrical stimulators (Model R-C1 TENS and EMS stimulator, Model R-E1 EMS stimulator and model R-T1 TENS Stimulator) is substantially equivalent to the predicate devices.