September 7, 2018

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

Re: K181688
Trade/Device Name: R-C1 TENS and EMS Stimulator; R-E1 EMS Stimulator; R-T1 TENS Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: June 6, 2018
Received: June 26, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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)*
K181688

Device Name
R-C1 TENS and EMS Stimulator; R-E1- EMS Stimulator; R-T1 TENS Stimulator

Indications for Use *(Describe)*

R-C1 TENS and EMS Stimulator
For TENS 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.

R-E1 EMS Stimulator
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.

R-T1 TENS Stimulator
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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Sponsor: Shenzhen Roundwhale Technology Co., Ltd
File No: RW-Stimulator A-FDAP-8
Date: Aug. 24, 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: _K181688__

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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Telephone: +86(755) 23212776
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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, For pain relief per 21 CFR § 882.5890

Device Class: Class II

Product Code: IPF, GZJ

b) Trade Name: R-E1, EMS Stimulator

Common Name: Powered Muscle Stimulator

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

Device Class: Class II

Product Code: IPF

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, For pain relief per 21 CFR § 882.5890

Device Class: Class II

Product Code: GZJ

3. Identification of Predicate Device(s)

Manufacturer	Famidoc Technology Co., Ltd
Legally Marketed Device	FDES101(ED401), FDES102(ED402), FDES103(ED403)
510 (K) Number	K113010

4. Description of Device

The RW Series A Electrical Stimulator, which includes models R-C1, R-E1 and R-T1, 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 stimulator is used with electrodes. For the electrodes are provided by the manufacturer Top-Rank Health Care Equipment Co. Ltd, cleared under K070612.

The three models of R-C1, R-E1 and R-T1 have the same appearance, structure, display, electrical principle and critical components, the main differences are software and color. The R-C1 have TENS mode (12 programs), EMS mode (9 programs). The R-E1 only have EMS mode (9 programs) and R-T1 only have TENS mode (12 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:

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.

R-E1, EMS Stimulator

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.

R-T1, TENS Stimulator

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

.

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 stimulator (R-C1, R-E1 and R-T1).

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

All the test results demonstrate RW series A Electrical stimulator (R-C1, R-E1 and R-T1) 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	Yes	Conform
Risk management	ISO 14971:2007	Yes	Conform

8. Comparison for Predicate Device & Subject Device

The RW series A Electrical stimulator (R-C1, R-E1 and R-T1) submitted in this 510(k) file is substantially equivalent in intended use, design, technology/ principles of operation, materials and performance to the cleared Electrical stimulator models FDES101(ED401), FDES102(ED402) and FDES103(ED403) (K113010). 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-C1 TENS and EMS Stimulator	**R-E1 EMS Stimulator**	**R-T1 TENS Stimulator**	**FDES101 (ED401) TENS and EMS Stimulator**	**FDES102 (ED402) TENS Stimulator**	**FDES103 (ED403) EMS Stimulator**	
510K#	K181688			K113010			N/A
Manufacturer	Shenzhen Roundwhale Technology Co., Ltd.			Famidoc Technology Co., Ltd			N/A
Number of output models	TENS and EMS	EMS	TENS	TENS and EMS	TENS	EMS	
Intended use	***For TENS 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.			***For TENS 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.			Same

Comparison item	New device			Predicate device			Substantial equivalence determination
	R-C1 TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	FDES101 (ED401) TENS and EMS Stimulator	FDES102 (ED402) TENS Stimulator	FDES103 (ED403) EMS Stimulator	
Prescription or OTC	Prescription	Prescription	Prescription	Prescription	Prescription	Prescription	Same
FDA product code	IPF, GZJ	IPF	GZJ	IPF, GZJ	GZJ	IPF	Same
Basic technological characteristics							
Power source	Battery powered, d.c. 6.0V, 4 X AAA batteries			Battery powered, d.c. 6.0V, 4 X AAA batteries			Same
User interface	By LCD display			By LCD display			Same
Output channel	Two channels			Two channels			Same
Number of treatment programs	For TENS: 12 For EMS: 9	9	12	For TENS: 15; For EMS: 15	15	15	N/A
Number of output channels / Synchronous or Alternating?	Alternating			Synchronous an 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
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

Comparison item		New device			Predicate device			Substantial equivalence determination
		R-C1 TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	FDES101 (ED401) TENS and EMS Stimulator	FDES102 (ED402) TENS Stimulator	FDES103 (ED403) EMS Stimulator	
Patient Override Control?		No			No			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			0-60 minutes			Different but does not adversely impact safety and effectiveness of subject device
Patient Leakage Current	- Normal condition (uA)	11.4 uA	11.4 uA	11.4 uA	3.0uA			SE, meet the requirements of IEC 60601-1
	- Single fault condition (uA)	9.6uA	9.6uA	9.6uA	5.8uA			
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	EMS: 0 No output no pulse applied	TENS: 0 No output no pulse applied	TENS: 0 EMS: N/A No output no pulse applied	TENS: 0 No output no pulse applied	EMS: 0 No output no pulse applied	Same
Housing materials construction		Plastic (ABS) enclosure			Plastic (ABS) enclosure			Same

Comparison item		New device			Predicate device			Substantial equivalence determination
		R-C1 TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	FDES101 (ED401) TENS and EMS Stimulator	FDES102 (ED402) TENS Stimulator	FDES103 (ED403) EMS Stimulator	
Treatment area		Any area (Except those treatment area which been described in the user manual can not use), such as Hand, Arm, Chest, Waist, Buttock, Thigh, Calf, Back and low back etc.			Any area (Except those treatment area which been described in the user manual can not use), such as Hand, Arm, Chest, Waist, Buttock, Thigh, Calf, Back and low back etc.			Same
List of applied part material(s)		Electrode – silica gel			Electrode – silica gel			Same
Compliance with 21 CFR 898?		Yes			Yes			Same
Electrode pads		Compliance with ISO 10993-1, provided by Top-Rank 50*50mm, Transparent silica gel			Compliance with ISO 10993-1, provided by Top-Rank 50*50mm, Transparent silica gel			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

Comparison item		New device			Predicate device			Substantial equivalence determination
		R-C1 TENS and EMS Stimulator	**R-E1 EMS Stimulator**	**R-T1 TENS Stimulator**	**FDES101 (ED401) TENS and EMS Stimulator**	**FDES102 (ED402) TENS Stimulator**	**FDES103 (ED403) EMS Stimulator**	
Compliance with Voluntary Standards?	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			0.35			Slightly different but does not impact safety and effectiveness of subject device
Dimensions(in.) [W × H × D] For unit		4.82x2.78x1.08			5.1x2.99x1.38			Slightly different but does not impact safety and effectiveness of subject device
Operating temperature and humidity		5℃~40℃; 15%RH~93%RH;			5℃~40℃; 30%RH~75%RH;			
Storage temperature and humidity		-10℃~55℃; 10%RH~90%RH;			-10℃~50℃; 10%RH~90%RH;			

Comparison item		New device			Predicate device			Substantial equivalence determination
		R-C1 TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	FDES101 (ED401) TENS and EMS Stimulator	FDES102 (ED402) TENS Stimulator	FDES103 (ED403) EMS Stimulator	
Output Specifications								
Waveform	TENS mode	Biphasic	N/A	Biphasic	Biphasic	Biphasic	N/A	Same
	EMS mode	Biphasic	Biphasic	N/A	Biphasic	N/A	Biphasic	Same
Shape	TENS mode	Square	N/A	Square	Square	Square	N/A	Same
	EMS mode	Square	Square	N/A	Square	N/A	Square	Same
Maximum output voltage (Vpp)	@500Ω	30	30	30	30	30	30	Same
	@2KΩ	108	108	108	90	90	90	Different but does not adversely impact safety and effectiveness of subject device
	@10KΩ	108	108	108	96	96	96	
Max Output Current (mA)	@500Ω	60	60	60	60	60	60	Same
	@2KΩ	54	54	54	45	45	45	Different but does not adversely impact safety and effectiveness of subject device
	@10KΩ	10.8	10.8	10.8	9.6	9.6	9.6	
Pulse Width Range(uS)		100-380uS	200-380uS	100-330uS	50-300us	50-300us	50-300us	
Frequency (Hz)		1-125Hz	1-110Hz	2-125Hz	0.5-150Hz	0.5-150Hz	1-150Hz	

Comparison item		New device			Predicate device			Substantial equivalence determination
		R-C1 TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	FDES101 (ED401) TENS and EMS Stimulator	FDES102 (ED402) TENS Stimulator	FDES103 (ED403) EMS Stimulator	
For multi-program waveforms only	Symmetrical phases?	Yes	Yes	Yes	Yes	Yes	Yes	Same
	Phase Duration	100-380uS	200-380uS	100-330uS	50-300uS	50-300uS	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	0	0	Same
Maximum Current Density (mA/cm^2, 500Ω, r.m.s)		2.4	2.4	2.4	2.4	2.4	2.4	Same
Maximum Phase Charge (uC, 500Ω)		22.8	22.8	19.8	18	18	18	Different but does not adversely impact safety and effectiveness of subject device
Max. average current (average absolute value, mA)		16.8	16.8	15.4	10.4	10.4	10.4	
Maximum Power Density (W/cm^2, 500Ω, r.m.s)		0.072	0.072	0.072	0.072	0.072	0.07009	

Comparison item		New device			Predicate device			Substantial equivalence determination
		R-C1 TENS and EMS Stimulator	R-E1 EMS Stimulator	R-T1 TENS Stimulator	FDES101 (ED401) TENS and EMS Stimulator	FDES102 (ED402) TENS Stimulator	FDES103 (ED403) EMS Stimulator	
Burst mode (i.e. pulse trains)	Pulses per burst	25	N/A	25	10	10	N/A	Different but does not adversely impact safety and effectiveness of subject device
	Bursts per second (Hz)	2	N/A	2	0.5,1,2,3,4,5	0.5,1,2,3,4,5	N/A	
	Burst duration	250ms	N/A	250ms	10ms	10ms	N/A	
	Duty cycle	500ms	N/A	500ms	10ms/100ms	10ms/ 100ms	N/A	
On time (s)		0.5-12	N/A	0.5-12	0-30	N/A	0-30	Similar and does not impact safety and effectiveness of subject device
OFF time (s)		0.5-1	N/A	0.5-1	0-30	N/A	0-30	
Electrode area (cm^2)		25	25	25	25	25	25	Same

Similarity and Difference

The RW series A Electrical stimulators (R-C1, R-E1 and R-T1) has been compared with “Electrical stimulator Models FDES101(ED401), FDES102(ED402) and FDES103(ED403)”. 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.

7. Conclusions

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