November 3, 2023

Shenzhen Roundwhale Technology Co., Ltd.
Amos Zou
RA Manager
202,2/F,Building 27, Dafa Industrial Park, Longxi community,
Longgang street, Longgang district
Shenzhen, Guangdong 518108
China

Re: K231440
Trade/Device Name: Combo Electrotherapy Device
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, LIH
Dated: September 27, 2023
Received: September 27, 2023

Dear Amos Zou:

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.

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,

Jitendra V. Virani -S

CDR Jitendra Virani, MS, MBA
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231440

Device Name
Combo Electrotherapy Device

Indications for Use *(Describe)*

Model:R-C101W:
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

Model:R-C101A
For TENS/IF 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 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

Model:R-C101B
For TENS/IF 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 preventvenous thrombosis

Model:R-C101E
For IF mode
1. Symptomatic relief of chronic intractable pain
2. Post traumatic pain

3. Post surgical pain

For 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 preventvenous thrombosis

Model:R-C101H

For TENS and IF mode

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

Model:R-C101D

For TENS mode

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

Model:R-C101G

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 muscles to preventvenous thrombosis

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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Traditional 510(k) Summary

510(k) number: K231440

1. Submitter of 510(K):

Sponsor

Company Name:	Shenzhen Roundwhale Technology Co., Ltd.
Address:	202,2/F,Building 27, Dafa Industrial Park, Longxi community, Longgang street, Longgang district, Shenzhen, China.
Contact person:	Zeng Chunming
TEL:	+86-755-23212776
FAX:	+86-755- 23212776
E-mail:	zcm@roovjoy.com
Date of Prepared:	November.01,2023

Application Correspondent:

Company Name:	Shenzhen Roundwhale Technology Co., Ltd.
Address:	202,2/F,Building 27, Dafa Industrial Park, Longxi community, Longgang street, Longgang district, Shenzhen, China.
Contact person:	Amos Zou
TEL:	+86-15015249549
E-mail:	amos.zou@139.copm

2. Proposed Device and code:

Device name:	Combo Electrotherapy Device
Model:	R-C101W,R-C101A,R-C101B,R-C101E,R-C101H,R-C101D,R-C101G
Primary Product Code:	IPF
Secondary Product Codes:	GZJ, LIH

Regulation number:	1) 21 CFR 890.5850 2) 21 CFR 882.5890 3) 21 CFR 882.5890

Regulation Name:	**1)** Powered muscle stimulator 2) Transcutaneous electrical nerve stimulator for pain relief 3) Transcutaneous electrical nerve stimulator for pain relief
Review panel:	1) Physical Medicine 2) Neurology 3) Neurology
Device class:	II
Type:	Traditional

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer	Product Code
K171978	Combo Stimulator LT7102	Shenzhen Dongdixin Technology Co., Ltd.	IPF,ZJ, LIH

4. Description of Proposed Device:

The Combo Electrotherapy Device (Models: R-C101W, R-C101A, R-C101B, R-C101E, R-C101H, R-C101D, and R-C101G) is a Transcutaneous Electrical Nerve Stimulator and muscle stimulator. The device features two independent output channels and four self-adhesive electrode gel pads. The stimulator sends a gentle electrical current to the underlying nerves and muscle groups via electrodes applied on the skin. Users can choose from pre-set programs or specify their own to suit their individual needs. All controls and indicators are controlled by software which also controls waveform characteristics.

The 7 models have similar housing with a viewable LCD display and an accessible keypad. The LCD is located on the upper half of the rectangular face of the device above the keypad. It is used to display system information to the user.

The device is battery-powered but can be connected to an external power supply for charging its internal battery which is a non-user serviceable or accessible 3.7V D.C., Li-ion battery.

There are only two external connections on the device - power input and electrode connector - with no connection to any other devices. The Battery Charger is not included in the package; however, users can choose adapters that meet IEC 60601-1 medical standards.

All of the accessories for use with this device are already marketed in the U.S. and are either Class II 510(k) exempt or Class II previously cleared devices. The accessories Include the following:

- The self-adhesive electrode (50mm x 50mm) with conductive media (gel) and Electrode Lead Wires is a Class II device that has been previously cleared (K222252,manufacturer: Shenzhen Roundwhale Technology Co., Ltd.). It can be packaged together with 510(k) cleared devices or separately as a replacement electrode for 510(k) cleared devices. The exact proportions of the ingredients used in the electrode patch/pad may be withheld as a trade secret.
- The electrode cable is a device composed of strands of insulated electrical conductors laid together around a central core and intended for medical purposes to connect an electrode from a patient to a diagnostic machine.(Submission Type:510(K) Exempt)
- USB Cable Is not a medical device, used to connect the external power supply to charge the lithium battery, The Battery Charger is not provided in the package, but users will choose adapters that meet the IEC 60601-1 medical standard.

The accessories can be packaged with 510(k) cleared devices or packaged separately as a replacement electrode for 510(k) cleared devices.

model	R-C101W	R-C101A	R-C101B	R-C101E	R-C101H	R-C101D	R-C101G

mode	TENS EMS RUSS MIC IF	TENS EMS RUSS IF	TENS EMS RUSS IF	RUSS IF	TENS IF	TENS	TENS EMS

5. Indications for Use

Model:R-C101W:

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

Model:R-C101A

For TENS/IF 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 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

Model:R-C101B

For TENS/IF 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

Model:R-C101E

For IF mode

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

For 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

Model:R-C101H

For TENS and IF mode

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

Model:R-C101D

For TENS mode

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

Model:R-C101G

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 muscles to prevent venous thrombosis

6. Technical and Performance

The following table compares the device to the predicate device with basic technological characteristics.

No.	Item	**Predicate device (**K171978)	**New device (K231440)**	**Discussion**
1	Device Name	Combo Stimulator LT7102	Combo Electrotherapy Device (Model:R-C101W,R-C101A,R- C101B,R-C101E,R-C101H,R-C101D,R-C101G)	N/A
2	Manufacturer	Shenzhen Dongdixin TechnologyCo., Ltd.	Shenzhen Roundwhale TechnologyCo., Ltd.	N/A
3	Type of use	Prescription	Prescription	Same
4	Indications for Use	**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 flowcirculation 3. Prevention or retardation ofdisuse atrophy 4. Muscle re-education 5. Maintaining or increasing rangeof motion. 6. Immediate post-surgical stimulation of muscles to prevent venous thrombosis	Model:R-C101W: 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 Model:R-C101A For TENS/IF 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 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	Same

No.	Item	**Predicate device (**K171978)	**New device (K231440)**	**Discussion**
			prevent venous thrombosis Model:R-C101B For TENS/IF 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 Model:R-C101E For IF mode 1. Symptomatic relief of chronic intractable pain 2. Post traumatic pain 3. Post surgical pain For 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 Model:R-C101H For TENS and IF mode 1) Symptomatic relief of chronic intractable pain. 2) Post traumatic pain. 3) Post surgical pain.	

No.	Item	**Predicate device (**K171978)	**New device (K231440)**	**Discussion**
			Model:R-C101D For TENS mode 1. Symptomatic relief of chronic intractable pain 2. Post traumatic pain 3. Post surgical pain Model:R-C101G 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 muscles to prevent venous thrombosis	
5	Power Source	3.7V Li-ion Battery Charger output:5.0V DC, 300mA	3.7 V Li-ion battery Charger Output: 5V DC, 300mA	Same
	Method of Line current isolation	N/A	NA	Same
	-Patient Leakage Current -Normal condition -Single fault condition	5 uA 5 uA	5 uA 5 uA	Same

No.	Item	**Predicate device (**K171978)	**New device (K231440)**	**Discussion**
6	Number of Output Modes	5	R-C101W:TEN/EMS/IF/RUSS/MIC RC101A:TENS/EMS/RUSS/IF R-C101B:TENS/EMS/RUSS/IF R-C101E:RUSS/IF R-C101H:TENS/IF R-C101D:TENS R-C101G:TENS/EMS	Different Note 1 The number of treatment programs only different by design; the core principles of these two devices are similar but does not adversely impact safety and effectiveness of subject device.
7	Number of Output Channels	2	2	Same
UN	- Synchronousor Alternating?	Synchronous andAlternating	Synchronous andAlternating	Same
	- Method of Channel Isolation?	By enclosure	By enclosure	Same
8	Constant Current? Constant Voltage?	Yes No	Yes No	Same
9	Software/Firmware/ Microproce ssor Control?	Yes	Yes	Same
10	Automatic Overload Trip? Automatic Over Current Trip?	Yes	Yes	Same
11	Automatic NoLoad Trip?	Yes	Yes	Same
12	AutomaticShut off?	Yes	Yes	Same
13	Patient Override Control?	No	No	Same
14	Indicator Display			

No.	Item	**Predicate device (**K171978)	**New device (K231440)**	**Discussion**
	-On/Off Status?	Yes	Yes	Same
	-Voltage/Current Level?	Yes	Yes	Same
	-Low Battery?	Yes	Yes	Same
15	Waveform TENS EMS Interferential Microcurrent Russian	 Biphasic Biphasic Biphasic Monophasic Biphasic	 MIC : Mono-phaseOther : Bi-phase	Same
16	Shape TENS EMS Interferential Microcurrent Russian	Square Square SquareSquare Square	Square Square Square Square Square	Same
17	Max Output Voltage (V) ±20%			
	500Ω TENS EMS Interferential Microcurrent Russian	 50 50 15.75 0.4 15.75	 45 45 15 0.35 45	Different Note 2 Based on the calculation refer Note 3 of maximum current density, maximum average power density , these parameters don't exceed the safety limit. and these parameters have passed IEC 60601-2-10 test codes. So these differences will not raise any new safety and effectiveness issues.
	2kΩ TENS EMS Interferential Microcurrent Russian	 102 102 33 1.6 33	 96 96 30 1.48 94	
	10kΩ TENS EMS Interferential Microcurrent Russian	Not publicly available	 96 96 30 1.48 94	
18	Max Output Current (mA) ±20%			

No.	Item	**Predicate device (**K171978)	**New device (K231440)**	**Discussion**
	500Ω TENS EMS Interferential Microcurrent Russian	 100 100 31.5 0.8 31.5	 90 90 30 0.7 90	Different Note 2 Based on the calculation refer Note 3 of maximum current density, maximum average power density , these parameters don't exceed the safety limit. and these parameters have passed IEC 60601-2-10 test codes. So these differences will not raise any new safety and effectiveness issues.
	2kΩ TENS EMS Interferential Microcurrent Russian	 51 51 16.5 0.8 16.5	 48 48 15 0.74 47	
	10kΩ TENS EMS Interferential Microcurrent Russian	Not publicly available	 9.6 9.6 3 0.148 9.4	
19	Pulse Width Range TENS EMS Interferential MicrocurrentRussian	TENS:50-400uS EMS:200~400uS IF:100/200/400uS MIC:2-200ms RUSS:400uS	TENS/EMS: 50 to 450 μs ; IF:50μs/100μs ; MIC: 2ms - 500msRUSS: 200μs	
20	Frequency TENS EMS Interferential MicrocurrentRussian	TENS:1~150Hz EMS:1~100Hz IF:2.5K,5K,10K HzMIC:1-150Hz RUSS:2.5kHz	TENS/EMS: 2 to 150 Hz ; IF: Carrier F 5KHz/10KHz Beat F1Hz -200Hz MIC: 0.1Hz - 150Hz RUSS: Carrier F 2.5KHz Burst F10Hz -70Hz	
21	Beat Frequency Interferential	 1-200Hz	 1-200Hz	Same
22	Maximum Phase Charge (uC, 500Ω)	TENS:2.40 EMS:2.40 IF: 0.79 MIC:0.48 RUSS:3.5	TENS: 2.73 EMS:2.73 IF: 0.75 MIC:0.42 RUSS:9	Different Note 3 have passed IEC 60601-2-10 test. the Maximum Current Density of the subject device is lower than 2 mA/cm^2 refers to "IEC60601-2-10 Clause 201.4.2" and the Maximum Average Power Density is less than 0.25 W/cm^2 refer to "Guidance Document for Powered Muscle Stimulator 510(k)s
	Maximum Current Density (mA/cm2, 500Ω, r.m.s)	 TENS: 0.24 EMS: 0.24 IF:0.63 MIC:0.01 RUSS:0.7	 TENS: 0.24 EMS: 0.24 IF:0.6 MIC:0.01 RUSS:1.8	

No.	Item	**Predicate device (**K171978)	**New device (K231440)**	**Discussion**
	Net Charge (μC) per pulse	Not publicly available	TENS: 0 μC @500Ω Method：Balanced waveform EMS: 0 μC @500Ω Method：Balanced waveform IF: 0 μC @500Ω Method：Balanced waveform MIC: 0 μC @500Ω Method：Balanced waveform RUSS: 0 μC @500Ω Method：Balanced waveform	
	Max.Average current (average absolute value, mA)	TENS: 6 EMS: 6 IF: 15.75 MIC:0.24 RUSS:17.5	TENS: 6.075 EMS: 6.075 IF:15 MIC:0.21 RUSS:45	
	Maximum Power Density (mW / cm2, 500Ω, r.m.s)	TENS: 0.72 EMS: 0.72 IF: 4.96 MIC:0.01 RUSS:6.13	TENS: 0.74 EMS: 0.74 IF: 4.5 MIC:0.01 RUSS:40.5	
	ON Time	Not publicly available	TENS: N/A EMS: 1-90 S IF: N/A MIC: N/A RUSS:1-90 S	Although the “on/off” time is slightly different for both devices it is compliant with FDA Guidance Document for Powered Muscle Stimulator 510(k)s and the difference between on and off time ranges doesn't impact essential performance, basic safety or substantial equivalence.
	OFF time	Not publicly available	TENS: N/A EMS: 1-90 S IF: N/A MIC: N/A RUSS: 1-90 S	
23	Electrode area (cm2)	25	25	Same
24	Timer Range (minutes)	5-90 minutes	5-90 minutes	Same
25	Compliancewith Voluntary Standards?	IEC60601-1, IEC60601-1-2, IEC60601-2-10	IEC60601-1, IEC60601-1-2, IEC60601-2-10	Same
26	Compliancewith 21 CFR 898?	Yes	Yes	Same
27	Weight (lbs.)	0.28	About 140 grams(0.31lbs)	Different, Note 4 Differences in physical and electronic component characteristics do not raise different questions of safety & effectiveness.
28	Dimensions H x WxL	4.6x2.36x0.9 inch	120.5 mm (L) x 69.5 mm (W) x 27mm (H)	

No.	Item	**Predicate device (**K171978)	**New device (K231440)**	**Discussion**
29	Housing Materials & Construction	Enclosure: ABS	Enclosure: ABS	Same
30	Burst Mode (i.e., pulse trains)			
	a. Pulses per burst	Not publicly available	TENS: 7 EMS: N/A IF: N/A MIC: N/A RUSS: N/A	Different but does not adversely impact safety and effectiveness of subject device
	b. Bursts per second	Not publicly available	TENS: 0.5, 1, 2, 3, 4, 5 EMS: N/A IF: N/A MIC: N/A RUSS: N/A	
	c. Burst duration (seconds)	Not publicly available	TENS: 70mS EMS: N/A IF: N/A MIC: N/A RUSS: N/A	
	d. Duty Cycle [Line (b) x Line (c)]	Not publicly available	TENS: 3.5% – 35% EMS: N/A IF: N/A MIC: N/A RUSS: N/A	
31	Description of Accessories			
	1. Electrodes	self-adhesive electrode (50mm x 50mm)	self-adhesive electrode (50mm x 50mm)	Same
	2. Electrode Conductive Medium (Gel)	self-adhesive electrode with conductive media (gel)	self-adhesive electrode with conductive media (gel)	Same
	3. Electrode Lead Wires and Patient Cables	self-adhesive electrode with Electrode Lead Wires	self-adhesive electrode with Electrode Lead Wires	Same
	4. Batteries	3.7V D.C.,Li-ion batteries	3.7V D.C.,Li-ion batteries	Same
	5. Battery Charger	NA	NA	Same

Comparison in Detail(s):

Note 1

The proposed device has more treatment programs than the predicate device K171978, all treatment programs ofproposed device are comparable to the mode 1 to mode 3 of the predicate device. The proposed device doesn't have treatment program to compare with the mode 4 to mode 6 of the predicate device because predicate device's mode 4 to mode 6 are variation waveform of the mode 1 to mode 3. All of the treatment programs have passed the IEC 60601-2-10 and AAMI / ANSI ES60601-1 test codes. So this difference doesn't raise any safety or effectiveness issue. And the weight, dimensions, appearance of proposed device are a little different from predicate device K171978, but these differences will not raise any safety or effectiveness issue.

Note 2: Difference in Maximum Output Voltage and Maximum Output Current

There are some differences on the maximum output voltage and maximum output current between the proposed device and predicate device. Based on the calculation refer Note 3 of maximum current density, maximum average power density , these parameters don't exceed the safety limit. 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 pulse width, pulse period and frequency 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 differences of function specification will not raise any safety or effectiveness issue.

Note 3: Difference in maximum current density, maximum average current and maximum power density

1) under TENS mode, Select the maximum frequency and pulse width in TENS mode for calculation: pulse width: 450uS, Frequency: 150 Hz, max output current: 90mA, electrodes: 50 x 50mm
   - Maximum Average Current=I Peak *F*P=90*150*450*/1000000=6.075mA
   - Maximum Current Density: =I Peak *F*P/S= 6.075/（5*5）=0.24mA/cm^2
   - Maximum Average Power Density=Maximum Current*Maximum Current*R /S=0.74mW/cm^2

2) under EMS mode, Select the maximum frequency and pulse width in TENS mode for calculation: pulse width: 450uS, Frequency: 150 Hz, max output current: 90mA, electrodes: 50 x 50mm
   - Maximum Average Current=I Peak *F*P=90*150*450/1000000=6.075mA
   - Maximum Current Density: =I Peak *F*P/S= 6.075/（5*5）=0.24mA/cm^2
   - Maximum Average Power Density=Maximum Current*Maximum Current*R /S=0.74mW/cm^2

3) under IF mode, Select the maximum frequency and pulse width in TENS mode for calculation: pulse width: 50uS, Frequency: 10000 Hz, max output current: 30mA, electrodes: 50 x 50mm
   - Maximum Average Current=I Peak *F*P=30 * 10000 * 50*/1000000=15mA
   - Maximum Current Density: =I Peak *F*P/S= 15/（5*5）=0.6mA/cm^2
   - Maximum Average Power Density=Maximum Current*Maximum Current*R /S=4.5mW/cm^2

4) under RUSS mode, Select the maximum frequency and pulse width in TENS mode for calculation: pulse width: 200uS, Frequency: 2500 Hz, max output current: 90mA, electrodes: 50 x 50mm
   - Maximum Average Current=I Peak *F*P=90*2500*200/1000000=45mA
   - Maximum Current Density: =I Peak *F*P/S= 45/（5*5）=1.8mA/cm^2
   - Maximum Average Power Density=Maximum Current*Maximum Current*R /S=40.5mW/cm^2

5) under MIC mode, Select the maximum frequency and pulse width in TENS mode for calculation: pulse width: 2mS, Frequency: 150 Hz, max output current: 0.7mA, electrodes: 50 x 50mm
   - Maximum Average Current=I Peak *F*P=0.7*150*20000*/1000000=0.21mA
   - Maximum Current Density: =I Peak *F*P/S= 0.21/（5*5）=0.01mA/cm^2
   - Maximum Average Power Density=Maximum Current*Maximum Current*R /S=0.01mW/cm^2

The proposed device and the predicate device have some differences in net charge, maximum current density ,maximum power density, bursts per second, burst duration and duty cycle .However,these parameters do not exceed the safety limit and have passed IEC 60601-2-10 test. the Maximum Current Density of the subject device is lower than 2 mA/cm^2 refers to "IEC60601-2-10 Clause 201.4.2" and the Maximum Average Power Density is less than 0.25 W/cm^2 refer to "Guidance Document for Powered Muscle Stimulator 510(k)s (page 16 section 3 "Maximum current density and power density values should be calculated using the conductive surface area of the smallest electrodes provided/recommended for use with the unit; sample calculations should be provided. The maximum power density should be based on the maximum duty cycle and should be averaged over an output duration of one second. The maximum power density should be less than 0.25 Watts/cm^2 to reduce the risk of thermal burns"Therefore, these differences will not pose any new safety or effectiveness risks.

Note 4 Weight and Dimensions

Differences in physical and electronic component characteristics do not raise different questions of safety & effectiveness.

7. Performance Testing:

Test Summary:

To establish substantial equivalence to the identified predicate devices, we performed the following tests on the subject device, Combo Electrotherapy Device serials.The testing results provide evidence that the device complies with the applicable standards requirement and it is substantially equivalent to the predicate devices.

Performance data includes “Non-Clinical Data”, brief description of which are shown as below.

7.1 Non-Clinical Data:

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrate that the proposed device complies with the following standards:

7.2 Biocompatibility testing

The new product Combo Electrotherapy Device (Model: R-C101W, R-C101A, R-C101B, R-C101E, R-C101H, R-C101D, R-C101G) has the same accessories-Self-Adhesive Electrode, it will have direct contact with human body only at intact skin, the maximum number of times the product can be used is 10-15 times. This information has been submitted by Shenzhen Roundwhale Technology Co., Ltd. (K222252), and it has been evaluated based on the ISO10993 standard and submitted to FDA.

7.3 Electrical Safety and EMC

Electrical safety and EMC testing were conducted on the Combo Electrotherapy Device (Model:R-C101W,R-C101A,R-C101B,R-C101E,R-C101H,R-C101D,R-C101G) ,, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1: 2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance for safety and the 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 standard for EMC.

7.4 Bench Testing

Bench testing was conducted on the Combo Electrotherapy Device (Model:R-C101W,R-C101A,R-C101B,R-C101E,R-C101H,R-C101D,R-C101G) ,consisting of all the accessories in the system. The system complies with the IEC 60601-1-11: 2015 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,and IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (Edition 2.1 2016-04)

7.5 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.

8. Clinical data:

No clinical testing was performed

9. Conclusions:

The proposed device has the same intended use and similar characteristics as the predicate device, Meanwhile, performance testing, bench testing, and safety report documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness.

Roundwhale Ltd. maintains that the Combo Electrotherapy Device is substantially equivalent to the predicate device in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.