January 22, 2024

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: K231423
Trade/Device Name: Combo Electrotherapy Device (Models: R-C101C, R-C101D, R-C101F, R-C101G, F100, MINI-TENS-COMB, RC101I, TENS3500)
Regulation Number: 21 CFR 882.5890; 21 CFR 890.5850
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, GZJ, IPF, NGX
Dated: September 5, 2023
Received: September 5, 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,

Robert Kang -S

for Pamela Scott, MS
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)*
K231423

Device Name
Combo Electrotherapy Device

Indications for Use *(Describe)*
Over-The-Counter Use:
a. Model R-C101C is indicated for OTC TENS and OTC EMS.
OTC TENS(NUH)
It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.
OTC EMS(NGX)
This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

b. Model R-C101D is indicated for OTC TENS.
It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

c. Model R-C101F is indicated for OTC TENS and OTC EMS.
OTC TENS(NUH)
It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.
OTC EMS(NGX)
This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

d. Model R-C101G is indicated for OTC TENS and OTC EMS.
OTC TENS(NUH)
It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.
OTC EMS(NGX)
This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

e. Model F100 is indicated for OTC TENS and OTC EMS.
OTC TENS(NUH)
It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.
OTC EMS(NGX)
This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

f. Model MINI-TENS-COMB is indicated for OTC TENS.
OTC TENS(NUH)
It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

g. Model R-C101I is indicated for OTC TENS.
OTC TENS(NUH)
It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

h. Model TENS3500 is indicated for OTC TENS.
OTC TENS(NUH)
It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

Prescription Use:
a. Model R-C101D is indicated for Rx TENS.
Rx TENS(GZJ)
1)Symptomatic relief of chronic intractable pain;
2)Post traumatic pain;
3)Post surgical pain;

b. Model R-C101G is indicated for Rx TENS and Rx EMS.
Rx TENS(GZJ)
1)Symptomatic relief of chronic intractable pain;
2)Post traumatic pain;
3)Post surgical pain;
Rx EMS(IPF):
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.

c. Model R-C101C, is indicated for Rx TENS and Rx EMS.
Rx TENS(GZJ) :
1)Symptomatic rlief of chronic intractable pain;
2)Post traumatic pain;
3)Post surgical pain;
Rx EMS(IPF):
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.

d. Model F100 is indicated for Rx TENS and Rx EMS.
Rx TENS(GZJ) :
1)Symptomatic relief of chronic intractable pain;
2)Post traumatic pain;
3)Post surgical pain;
Rx EMS(IPF):
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.

e. Model MINI-TENS-COMB is indicated for Rx TENS.
Rx TENS(GZJ) :

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

f. Model R-C101F is indicated for Rx TENS and Rx EMS.
Rx TENS(GZJ) :
1)Symptomatic relief of chronic intractable pain;
2)Post traumatic pain;
3)Post surgical pain;
Rx EMS(IPF):
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.

g. Model R-C101I is indicated for Rx TENS.
Rx TENS(GZJ) :
1)Symptomatic relief of chronic intractable pain;
2)Post traumatic pain;
3)Post surgical pain;

h. Model TENS3500 is indicated for Rx TENS.
Rx TENS(GZJ) :
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
- K231423

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

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:	December 11,2023

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
Date of Prepared:	December 11,2023

2. Proposed Device and code:

Device name:	Combo Electrotherapy Device							
Model:	R-C101C	R-C101D	R-C101F	R-C101G	F100	MINI-TENS-COMB	R-C101I,	TENS3500
associated claims	OTC TENS, OTC EMS	OTC TENS,	OTC TENS, OTC EMS	OTC TENS, OTC EMS	OTC TENS, OTC EMS	OTC TENS,	OTC TENS,	OTC TENS,
Classification product	NUH	NUH	NUH	NUH	NUH	NUH	NUH	NUH

code:								
Subsequent product code:	NGX	/	NGX	NGX	NGX	/	/	/
Regulation number:	1) 882.5890 2) 890.5850							

Device name:	Combo Electrotherapy Device							
Model:	R-C101C	R-C101D	R-C101F	R-C101G	F100	MINI-TENS-COMB	R-C101I,	TENS3500
associated claims	Rx TENS, Rx EMS	Rx TENS,	Rx TENS, Rx EMS	Rx TENS, Rx EMS	Rx TENS, Rx EMS	Rx TENS,	Rx TENS,	Rx TENS
Classification product code:	GZJ	GZJ	GZJ	GZJ	GZJ	GZJ	GZJ	GZJ
Subsequent product code:	IPF	/	IPF	IPF	IPF	/	/	/
Regulation number:	1)882.5890 2)890.5850							

3. Predicate Device:

Primary predicate device

510(K)	Trade or Proprietary or Model Name	Manufacturer	Product Code
K192087	Combo Electrotherapy Device	Shenzhen Roundwhale Technology Co., Ltd.	NUH,GZJ,IPF,NGX

Reference Predicate device

510(K)	Trade or Proprietary or Model Name	Manufacturer	Product Code
K181688&180956	TENS and EMS Stimulator R-C1	Shenzhen Roundwhale Technology Co., Ltd.	IPF, GZJ； NUH, NGX

4. Description of Proposed Device:

Combo Electrotherapy Device (Model:R-C101C,R-C101D,R-C101F,R-C101G,F100,MINI-TENS-COMB,R-C101I, TENS3500) are Transcutaneous Electrical Nerve Stimulator and muscle stimulator
The Device feature two independent output channels and four self-adhesive electrode gel pads. The stimulator sends gentle electrical current to underlying nerves and muscle group via electrode applied on the skin. They offer a wide range of functions for increasing general well- being, pain relief, maintaining physical fitness, relaxation.For these purpose, the user can either choose from pre-set programs or specify their own to suit the user's individual needs. Software controls all controls and indicators. Software controls waveform characteristics.

The 8 models have Similar housing with a viewable LCD display,an accessible keypad.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.The device is battery powered and can be connected to an external power supply for charging the internal battery. The battery is 3.7V D.C.,Li-ion batteries and is not user serviceable or accessible. The only external connections on the device are the power input and the electrode connector there is no connection to any other device. The Battery Charger is not provided in the package, but users will choose adapters that meet the IEC 60601-1 medical standard.

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:

- self-adhesive electrode (50mm x 50mm) with conductive media (gel) and Electrode Lead Wires that is a Class II previously approved device. (K222252， manufacturer:Shenzhen Roundwhale Technology Co., Ltd.)， and can be packaged with 510(k) cleared devices or packaged 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.

- An 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,submission type:510(k) Exempt,device class:2, Regulation Number:890.1175

- 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.

5. Indications for Use

Over-The-Counter Use:

a. Model R-C101C is indicated for OTC TENS and OTC EMS.

OTC TENS (NUH)

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

OTC EMS (NGX)

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

b. Model R-C101D is indicated for OTC TENS.

OTC TENS(NUH)

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

c. Model R-C101F is indicated for OTC TENS and OTC EMS.

OTC TENS(NUH)

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

OTC EMS(NGX)

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

d. Model R-C101G is indicated for OTC TENS and OTC EMS.

OTC TENS(NUH)

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

OTC EMS(NGX)

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

e. Model F100 is indicated for OTC TENS and OTC EMS.

OTC TENS(NUH)

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

OTC EMS(NGX)

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

f. Model MINI-TENS-COMB is indicated for OTC TENS.

OTC TENS(NUH)

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

g. Model R-C101I is indicated for OTC TENS.

OTC TENS(NUH)

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

h. Model TENS3500 is indicated for OTC TENS.

OTC TENS(NUH)

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

Prescription Use:

a. Model R-C101D is indicated for Rx TENS.

Rx TENS(GZJ).

1)Symptomatic relief of chronic intractable pain;

2)Post traumatic pain;

3)Post surgical pain;

b. Model R-C101G is indicated for Rx TENS and Rx EMS.

Rx TENS(GZJ):

1)Symptomatic relief of chronic intractable pain;

2)Post traumatic pain;

3)Post surgical pain;

Rx EMS(IPF):

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.

c. Model R-C101C, is indicated for Rx TENS and Rx EMS.

Rx TENS(GZJ):

1)Symptomatic relief of chronic intractable pain;

2)Post traumatic pain;

3)Post surgical pain;

Rx EMS(IPF):

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.

d. Model F100 is indicated for Rx TENS and Rx EMS.

Rx TENS(GZJ):

1)Symptomatic relief of chronic intractable pain;

2)Post traumatic pain;

3)Post surgical pain;

Rx EMS(IPF):

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.

e. Model MINI-TENS-COMB is indicated for Rx TENS.

Rx TENS(GZJ):

1)Symptomatic relief of chronic intractable pain;

2)Post traumatic pain;

3)Post surgical pain;

f. Model R-C101F is indicated for Rx TENS and Rx EMS.

Rx TENS(GZJ):

1)Symptomatic relief of chronic intractable pain;

2)Post traumatic pain;

3)Post surgical pain;

Rx EMS(IPF):

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.

g. Model R-C101I is indicated for Rx TENS.

Rx TENS(GZJ):

1)Symptomatic relief of chronic intractable pain;

2)Post traumatic pain;

3)Post surgical pain;

h. Model TENS3500 is indicated for Rx TENS.

Rx TENS(GZJ):

1)Symptomatic relief of chronic intractable pain;

2)Post traumatic pain;

3)Post surgical pain;

6. Technical and Performance

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

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
510(K)	K192087	K181688&180956	K231423	/
Device Name	Combo Electrotherapy Device, model R-C3,R-C4A, R-C4B, R-C4C and R-C4D	TENS and EMS Stimulator R-C1	Combo Electrotherapy Device, Model:R-C101C,R-C101D,R-C101F,R-C101G, F100,MINI-TENS-COMB,R-C101I, TENS3500)	/
Manufacturer	Shenzhen Roundwhale Technology Co., Ltd.	Shenzhen Roundwhale Technology Co., Ltd.	Shenzhen Roundwhale Technology Co., Ltd.	/
Prescription or OTC	OTC & Prescription	Prescription & OTC	OTC & Prescription	Same
FDA product code	NUH, NGX, IPF, GZJ	IPF, GZJ；NUH, NGX	NUH, NGX, IPF, GZJ	Same
Intended Use	Over-The-Counter Use: TENS mode: It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. EMS mode: This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance Prescription Use: For TENS mode: 1)Symptomatic relief of chronic intractable pain; 2)Post traumatic pain;	Over-the-Counter 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. Prescription Use: For TENS mode: 1)Symptomatic relief of chronic intractable pain; 2)Post traumatic pain;	Over-The-Counter Use: a. Model R-C101C is indicated for OTC TENS and OTC EMS. OTC TENS(NUH) It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. OTC EMS(NGX) This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance. b. Model R-C101D is indicated for OTC TENS.	Same

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
	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.	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.	OTC TENS(NUH) It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. c. Model R-C101F is indicated for OTC TENS and OTC EMS. OTC TENS(NUH) It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. OTC EMS(NGX) This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance. d. Model R-C101G is indicated for OTC TENS and OTC EMS. OTC TENS(NUH) It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.	

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
			OTC EMS(NGX) This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance. e. Model F100 is indicated for OTC TENS and OTC EMS. OTC TENS(NUH) It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. OTC EMS(NGX) This mode is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance. f. Model MINI-TENS-COMB is indicated for OTC TENS. OTC TENS(NUH) It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. g. Model R-C101I is indicated for OTC TENS. OTC TENS(NUH)	

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
			It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. h. Model TENS3500 is indicated for OTC TENS. OTC TENS(NUH) It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. Prescription Use: a. Model R-C101D is indicated for Rx TENS. Rx TENS(GZJ). 1)Symptomatic relief of chronic intractable pain; 2)Post traumatic pain; 3)Post surgical pain; b. Model R-C101G is indicated for Rx TENS and Rx EMS. Rx TENS(GZJ): 1)Symptomatic relief of chronic	

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
			intractable pain; 2)Post traumatic pain; 3)Post surgical pain; Rx EMS(IPF): 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. c. Model R-C101C, is indicated for Rx TENS and Rx EMS. Rx TENS(GZJ): 1)Symptomatic relief of chronic intractable pain; 2)Post traumatic pain; 3)Post surgical pain; Rx EMS(IPF): 1)Relaxation of muscle spasm; 2)Increase of local blood flow	

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
			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. d. Model F100 is indicated for Rx TENS and Rx EMS. Rx TENS(GZJ): 1)Symptomatic relief of chronic intractable pain; 2)Post traumatic pain; 3)Post surgical pain; Rx EMS(IPF): 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	

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
			thrombosis. e. Model MINI-TENS-COMB is indicated for Rx TENS. Rx TENS(GZJ): 1)Symptomatic relief of chronic intractable pain; 2)Post traumatic pain; 3)Post surgical pain; f. Model R-C101F is indicated for Rx TENS and Rx EMS. Rx TENS(GZJ): 1)Symptomatic relief of chronic intractable pain; 2)Post traumatic pain; 3)Post surgical pain; Rx EMS(IPF): 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;	

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
			6)Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. g. Model R-C101I is indicated for Rx TENS. Rx TENS(GZJ): 1)Symptomatic relief of chronic intractable pain; 2)Post traumatic pain; 3)Post surgical pain; h. Model TENS3500 is indicated for Rx TENS. Rx TENS(GZJ): 1)Symptomatic relief of chronic intractable pain; 2)Post traumatic pain; 3)Post surgical pain;	
Power source	R-C3, R-C4A and R-C4C:DC 3.7 V /600mAh Li-ion battery R-C4B and R-C4D: DC 4.5V, 3 ×AAA batteries	Battery powered, d.c. 6.0V, 4 X AAA batteries	R-C101D,R-C101G,R-C101C,F100,MINI-TENS-COMB:3.7V D.C.,Li-ion batteries R-C101F,R-C101I,TENS3500:9V batteries	Similar, but the subject device is in compliance with requirements of IEC 60601-1
User Interface	By LCD display	By LCD display	By LCD display	Same
Output Channel	Two channels	Two channels	Two channels	Same

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
Number of treatment programs	R-C3, R-C4C and R-C4D: 9 TENS, 8 EMS; R-C4A: 30 TENS, 27 EMS; R-C4B: 10 TENS, 9 EMS	For TENS: 12 For EMS: 9	R-C101D: TENS:30 R-C101G: TENS:30,EMS:20 R-C101C: TENS:30,EMS:20 F100: TENS:1,EMS:1 R-C101F: TENS:5,EMS:2 MINI-TENS-COMB: TENS:1 OR EMS:1 R-C101I: TENS:12 TENS3500: TENS:3	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
Synchronous or Alternating?	Synchronous and alternating	Synchronous and alternating	alternating	Same
Method of channel isolation	By electrical circuit and software	By electrical circuit and software	software	Same
Constant Current or Constan Voltage?	Constant voltage	Constant voltage	Constant voltage	Same
Waveform	Biphasic square	Biphasic square	Biphasic square	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Same
Automatic overload trip?	Yes	Yes	Yes	Same
Automatic Over Current Trip?	Yes	Yes	Yes	Same
Automatic No Load Trip?	Yes	Yes	Yes	Same
Automatic shut off?	Yes	Yes	Yes	Same

Item		Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
Patient Override Control?		Yes	Yes	Yes	Same
Indicator display	On/off status	Yes	Yes	Same	Same
	Low battery	Yes	Yes	Same	Same
	Intensity level	Yes	Yes	Same	Same
Time range(min)		For R-C3, R-C4C and R-C4D:30min, non-adjustable; For R-C4A and R-C4B:5-90min, adjustable	Nonadjustable 28 minutes	For R-C101C,R-C101D,R-C101G and F100: 5-90 min, adjustable; for MINI-TENS COMB: 20min ; for R-C101I, ,R C101F, TENS3500 1-60 min and continue ,adjustable)	Similar, Although the "Timer Range" of the subject device are little different from the predicate device, the time range of the subject device is included in the time range of the predicate device, So, the difference will not raise any safety or effectiveness issue.
Patient Leakage Current	Normal condition(uA)	R-C3, R-C4A and R-C4C:50uA R-C4B and R-C4D:53uA	11.4 uA	Patient Leakage Current (P)： 5 uA Patient Leakage Current with mains on the F-type applied parts (PM) : 9 uA	Different Note 1
	Single fault condition(uA)	R-C3, R-C4A and R-C4C: 31uA R-C4B and R-C4D: 58uA	9.6uA	Patient Leakage Current (P)： 172 uA Patient Leakage Current with mains on the F-type applied parts (PM) : 132 uA	
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: 0 EMS: 0 No output no	TENS: 0 EMS: 0 No output no pulse applied	Same

Item		Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
			pulse applied		
Housing materials construction		Plastic (ABS) enclosure	Plastic (ABS) enclosure	Plastic (ABS) enclosure	Same
Treatment area		For TENS: Any area (Except those treatment areas which cannot be applied as described in the user manual), such as neck, shoulder, back, joint, hip, hand, abdomen, upper extremities (arm) and lower extremities (leg); For EMS: Any area (except those treatment areas which cannot be applied as described in the user manual)	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.	For TENS: Any area(Except those treatment areas which cannot be applied as described in the user manual), such as neck, shoulder, back, joint, hip, hand, abdomen, upper extremities (arm) and lower extremities (leg); For EMS: Any area (except those treatment areas which cannot be applied as described in the user manual)	Same
List of applied part material(s)		Electrode – silica gel	Electrode – silica gel	Electrode – silica gel	Same
Compliance with 21 CFR 898?		Yes	Yes	Yes	Same
Classification	Type of protection against electric shock	Internally powered equipment	Internally powered equipment	Internally powered equipment	Same
	Degree of protection against Electric shock	Type BF applied part	Type BF applied part	Type BF applied part	Same
Device Class		Class II	Class II	Class II	Same

Item		Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
Compliance with Voluntary Standards?	Mechanical Safety	Compliant with requirements of IEC 60601-1, IEC 60601-2-10 safety standards	Compliant with requirements of IEC 60601-1, IEC 60601-2-10 safety standards	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	Compliant with requirements of IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2 safety standards	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	The delivered energy is limited according to requirements of collateral IEC 60601-2-10 safety standards	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	Compliant with requirements of IEC 60601-11 safety standard	Compliant with requirements of IEC 60601-11 safety standard	Same
Applied part		Electrode pad	Electrode pad	Electrode pad	Same
Operating temperature and humidity		5℃~40℃; 15%RH~93%RH;	5℃~40℃; 15%RH~93%RH;	5℃~40℃; 15%RH~93%RH;	Same
Storage temperature and humidity		-10℃~55℃; 10%RH~90%RH;	-10℃~55℃; 10%RH~90%RH;	-10℃~55℃; 10%RH~90%RH;	Same
Waveform	TENS mode	Biphasic	Biphasic	Biphasic	Same
	EMS mode	Biphasic	Biphasic	Biphasic	Same
Shape	TENS mode	Square	Square	Square	Same
	EMS mode	Square	Square	Square	Same
Maximum output voltage (Vpp)	@500Ω	66.4	30	46.4	Different Note 2
	@2KΩ	106	108	94	
	@10KΩ	106	108	94	
Max Output	@500Ω	132.8	60	92.8	

Item		Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
Current (mA)	@2KΩ	53	54	47	
	@10KΩ	10.6	10.8	9.4	
Pulse Width Range(uS)		R-C3, R-C4C and R-C4D:150~300Us R-C4A and R-C4B: 55-300uS	100-380uS	50-450uS	
Frequency (Hz)		R-C3, R-C4C and R-C4D: 2~100Hz R-C4A and R-C4B: 2~120Hz	1-125Hz	2-150 Hz	
For multi-program waveforms only	Symmetrical phases?	Yes	YES	Yes	Same
	Phase Duration	R-C3, R-C4C and R-C4D:150~300Us R-C4A and R-C4B: 55-300uS	100-380uS	50-450uS	Different but does not adversely impact safety And effectiveness of subject device
Net Charge per pulse cycle (uC, 500Ω)		0	0	0	Same
Maximum Phase Charge (uC, 500Ω)		TENS mode: R-C3, R-C4C and R-C4D:0.15 R-C4A: 0.15 R-C4B: 0.14	22.8	2.73	Different Note 3
		EMS Model: R-C3, R-C4C and R-C4D:0.13 R-C4A and R-C4B: 0.15	22.8	2.73	
Maximum Current Density (mA/cm2, 500Ω, r.m.s)		0.15	2.4	0.24	

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
Max.Average current (average absolute value, mA)	TENS mode: R-C3, R-C4C and R-C4D:3.74 R-C4A: 3.74 R-C4B: 3.46	16.8	6.075	
	EMS mode: R-C3, R-C4C and R-C4D:3.36 R-C4A and R-C4B: 3.84	16.8	6.075	
Maximum Power Density (W/cm2, 500Ω, r.m.s)	TENS mode: R-C3, R-C4C and R-C4D: 0.28 mW/cm^2 R-C4A: 0.28 mW/cm^2 R-C4B: 0.24 mW/cm^2	0.072	0.74 mW/cm^2	
	EMS mode: R-C3, R-C4C and R-C4D: 0.23 mW/cm^2 R-C4A: 0.29 mW/cm^2 R-C4B: 0.29 mW/cm^2	0.072	0.74 mW/cm^2	
Electrode area (cm2)	25	25	25	Same
a. Pulses per burst	25	25	25	Same
b. Bursts per second	2	2	2	Same
c. Burst duration (seconds)	250ms	250ms	250ms	Same
d. Duty Cycle [Line (b) x Line (c)]	500ms	500ms	500ms	Same
1. Electrodes	self-adhesive electrode (50mm x 50mm)	self-adhesive electrode (50mm x 50mm)	self-adhesive electrode (50mm x 50mm)	Same

Item	Primary predicate device (K192087)	Reference Predicate device (K181688&180956)	Subject Device (K231423)	Discussion
2. Electrode Conductive Medium (Gel)	self-adhesive electrode with conductive media (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	self-adhesive electrode with Electrode Lead Wires	Same
4. Batteries	R-C3, R-C4A and R-C4C:DC 3.7 V /600mAh Li-ion battery R-C4B and R-C4D: DC 4.5V, 3 ×AAA batteries	Battery powered, d.c. 6.0V, 4 X AAA batteries	R-C101D,R-C101G,R C101C,F100, MINI-TENS-COMB:3.7V D.C.,Li-ion batteries R-C101F,R-C101I,TENS3500:9V batteries	Similar, but the subject device is in compliance with requirements of IEC 60601-1
5. Battery Charger	NA	NA	NA	Same

Analysis for the differences:

Note 1: difference in Patient Leakage Current

The patient leakage current **under SINGLE FAULT CONDITION** of the subject devices is higher than the predicate, but it meets the requirements of IEC 60601-1. According to requirements of Table 3 of 8.7.3 Allowable values, IEC 60601-1(see the table below), for type BF (a.c.) devices, patient leakage current **under SINGLE FAULT CONDITION** should be less than 500 uA. Though patient leakage current **under SINGLE FAULT CONDITION** of our devices is different from the predicate device, it is below 500 uA and meets the requirements of IEC 60601-1, which demonstrate the subject device does not cause any safety or effectiveness risks.

Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION

Current in μA

Current	Description	Reference	Measuring Circuit		TYPE B APPLIED PART		TYPE BF APPLIED PART		TYPE CF APPLIED PART	
					NC	SFC	NC	SFC	NC	SFC
PATIENT AUXILIARY CURRENT		8.7.4.8	Figure 19	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7 a)	Figure 15	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
	Caused by an external voltage on a SIP/SOP	8.7.4.7 c)	Figure 17	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
Total PATIENT LEAKAGE CURRENT [a]	With the same types of APPLIED PART connected together	8.7.4.7 a) and 8.7.4.7 h)	Figure 15 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100
	Caused by an external voltage on a SIP/SOP	8.7.4.7 c) and 8.7.4.7 h)	Figure 17 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100

Key
NC = NORMAL CONDITION
SFC = SINGLE FAULT CONDITION

NOTE 1 For EARTH LEAKAGE CURRENT see 8.7.3 d).

NOTE 2 For TOUCH CURRENT see 8.7.3 c).

[a] Total PATIENT LEAKAGE CURRENT values are only applicable to equipment having multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS shall comply with the PATIENT LEAKAGE CURRENT values.

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 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

Above all, although There are some differences on the net charge, maximum current density ,maximum power density, bursts per second, burst duration and duty cycle between the proposed device and the predicate device,but these parameters don't 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/cm2 refers to "IEC60601-2-10 Clause 201.4.2" and the Maximum Average Power Density is less than 0.25 W/cm2 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/cm2 to reduce the risk of thermal burns.") ,Therefore, these differences won't raise any new safety and effectiveness risk.

Discussion:

By the comparison between items of new device and those of predicate devices one by one as listed in above tables, it can be seen that, all different items would not adversely impact safety and effectiveness of the subject device as the reasons are listed in the above table.

The RW series C Combo Electrotherapy Device (Model:R-C101C,R-C101D,R-C101F,R-C101G, F100,MINI-TENS-COMB,R-C101I,TENS3500) has been compared with RW series B Combo Electrotherapy Device (R-C3, R-C4A, R-C4B, R-C4C and R-C4D,K192087). The subject device has many Same and Similar items as that predicate devices, such as intended use, principle of operation, technological characteristics etc. Although there are several specifications that are different among those two devices, the comparison analysis has been completed to demonstrate that the differences among 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.

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 serial,and 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-C101C,R-C101D,R-C101F,R-C101G,F100,MINI-TENS-COMB,R-C101I, TENS3500) 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. which had been submitted with Shenzhen Roundwhale Technology Co., Ltd.(K222252) which has been evaluated based on the ISO10993 standard and submitted to FDA.

7.3 Safety and EMC

Electrical safety and EMC testing were conducted on the Combo Electrotherapy Device (Model:R-C101C,R-C101D,R-C101F,R-C101G,F100,MINI-TENS-COMB,R-C101I, TENS3500),, 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-C101C,R-C101D,R-C101F,R-C101G,F100,MINI-TENS-COMB,R-C101I, TENS3500),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 devices in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.