U.S. FOOD & DRUG ADMINISTRATION

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January 11, 2024

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

Re: K232995
Trade/Device Name: Neurological Therapy Devices - Accessories: Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning, AC1001, AC1002, AC1003, AC1003, AC1004, AC1005; Electrotherapy device Electrode belt for back of body, AC2001, AC2002, AC2003, AC2004; Electrotherapy device Electrode belt for Body joints, AC3001, AC3008, AC3009, AC3010, AC3011; Electrotherapy device Electrode for Knee, AC3002, AC3004, AC3006; Electrotherapy device Electrode for Elbow, AC3003, AC3005, AC3007; Electrotherapy device Electrode for gloves, AC4001, AC4002, AC4003; Electrotherapy device Electrode socks, AC5001, AC5002, AC5003; Electrotherapy device Electrode belt for arm of body, AC7001, AC7002, AC7003; Electrotherapy device Electode belt for back of body, AC8001; Electrode device Electrode belt for shoulder of body, AC9001

Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 12, 2023
Received: December 12, 2023

Dear Zou Amos:

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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232995

Device Name

Neurological Therapy Devices - Accessories:
AC1001 Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning,
AC1002 Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning,
AC1003 Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning,
AC1004 Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning,
AC1005 Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning,
AC2001 Electrotherapy device Electrode belt for back of body,
AC2002 Electrotherapy device Electrode belt for back of body,
AC2003 Electrotherapy device Electrode belt for back of body,
AC2004 Electrotherapy device Electrode belt for back of body,
AC3002 Electrotherapy device Electrode for Knee,
AC3004 Electrotherapy device Electrode for Knee,
AC3006 Electrotherapy device Electrode for Knee,
AC3003 Electrotherapy device Electrode for Elbow,
AC3005 Electrotherapy device Electrode for Elbow,
AC3007 Electrotherapy device Electrode for Elbow,
AC3001 Electrotherapy device Electrode belt for Body joints,
AC3008 Electrotherapy device Electrode belt for Body joints,
AC3009 Electrotherapy device Electrode belt for Body joints,
AC3010 Electrotherapy device Electrode belt for Body joints,
AC3011 Electrotherapy device Electrode belt for Body joints,
AC4001 Electrotherapy device Electrode gloves,
AC4002 Electrotherapy device Electrode gloves,
AC4003 Electrotherapy device Electrode gloves,
AC5001 Electrotherapy device Electrode socks,
AC5002 Electrotherapy device Electrode socks,
AC5003 Electrotherapy device Electrode socks,
AC7001 Electrotherapy device Electrode belt for arm of body,
AC7002 Electrotherapy device Electrode belt for arm of body,
AC7003 Electrotherapy device Electrode belt for arm of body,
AC8001 Electrotherapy device Electrode belt for back of body,
AC9001 Electrotherapy device Electrode belt for shoulder of body,

Indications for Use *(Describe)*

The Neurological Theray Devices - Accessories including Garment electrodes which are intended to be used with legally marketed electrical stimulating devices such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The cutaneous electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. The Garment electrodes including glove, socks, sleeve, knee belt and back belt which are made up of silver or conductive silicone rubber.

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 - K232995

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:	September 20,2023

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:	September 20,2023

2. Proposed Device and code:

Device name:	Neurological Therapy Devices - Accessories
Model:	AC3002Electrotherapy device Electrode for Knee, AC3004Electrotherapy device Electrode for Knee, AC3006Electrotherapy device Electrode for Knee, AC3003 Electrotherapy device Electrode for Elbow, AC3005Electrotherapy device Electrode for Elbow, AC3007Electrotherapy device Electrode for Elbow, AC4001Electrotherapy device Electrode gloves, AC4002Electrotherapy device Electrode gloves,

	AC4003Electrotherapy device Electrode gloves, AC5001Electrotherapy device Electrode socks, AC5002Electrotherapy device Electrode socks, AC5003Electrotherapy device Electrode socks AC1001Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning, AC1002Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning, AC1003Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning, AC1004Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning, AC1005Electrotherapy device Electrode belt for Abdominal Muscle Trainer Toning, AC2001Electrotherapy device Electrode belt for back of body, AC2002Electrotherapy device Electrode belt for back of body, AC2003Electrotherapy device Electrode belt for back of body, AC2004Electrotherapy device Electrode belt for back of body, AC3001Electrotherapy device Electrode belt for Body joints, AC3008Electrotherapy device Electrode belt for Body joints, AC3009Electrotherapy device Electrode belt for Body joints, AC3010Electrotherapy device Electrode belt for Body joints, AC3011Electrotherapy device Electrode belt for Body joints, AC7001Electrotherapy device Electrode belt for arm of body, AC7002Electrotherapy device Electrode beltfor arm of body, AC7003Electrotherapy device Electrode beltfor arm of body, AC8001Electrotherapy device Electrode belt for back of body, AC9001Electrotherapy device Electrode belt for shoulder of body,
Regulation Medical Specialty	Neurology
Product Code	GXY
Regulation Number	882.1320
Device class:	II
Sterilization facility	Not applicable
Type:	Traditional

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K203158	BioWave BioWraps	BioWave Corporation
K171798	Silverwear Silver Pro Garment Device	Media Plus, LLC
K171721	Electrodes with Silver Conductive	Shenzhen Konmed Technology, Co. LTD.

4. Description of Proposed Device:

The Neurological Therapy Devices - Accessories -Conductive fiber(Model:Electrotherapy device Electrode for Knee, Electrotherapy device Electrode for Elbow, Electrotherapy device Electrode gloves, Electrotherapy device Electrode socks,Neurological physiotherapy devices-accessories), are conductive garments that are made from material which is knitted from primarily nylon yarn with minor amounts of lycra, spandex to achieve a stretch fabric for a snug garment fit polyester for tactile qualities and polyester sheathed carbon yarn and pure silver coated nylon fibers to provide conductivity. The knitting follows standard knitting procedures with the conductive knitted material being fabricated into Neurological Therapy Devices - Accessories garments which are provided in multiple sizes of various garment configurations including; gloves, bands, socks, and sleeves.

The Neurological Therapy Devices - Accessories-conductive silicone rubber(Model:Electrotherapy device Electrode belt for back of body, Electrotherapy device Electrode belt for Abdominal Muscle TrainerToning, Electrotherapy device Electrode belt for Body joints,Electrotherapy device Electrode belt for arm of body,Electrotherapy device Electrode belt for back of body,Electrotherapy device Electrode belt for shoulder of body,Neurological physiotherapy devices-accessories), is made of conductive silicone rubber coated in conductive garments material, has excellent conductive performance and good flexibility and plasticity, can adapt to the needs of different shapes and sizes of electrodes.

The stretch characteristics of the material provide sufficient elasticity to ensure firm surface contact with the skin. The design of the devices is such that they can be used skin by reversing the surface contacting the skin.

The Neurological Therapy Devices - Accessories utilize conductive fibers or conductive silicone rubber as a conduit for current transmission. When current passes through the garment electrodes, the conductive fibers or conductive silicone rubber transmit the current to the surface of the body, thus enabling the transmission of current.The entire surface of the Neurological Therapy Devices - Accessories is very conductive having a resistance of less than 7 ohms per inch. This provides low current density with uniform current distribution to enable efficient use of these Neurological Therapy Devices - Accessories for use in TENS (transcutaneous electrical nerve stimulators) and NMES (powered muscle stimulator devices).

The Neurological Therapy Devices - Accessories are non- sterile external devices which are designed for single patient, for multiple uses and are intended for Prescription Use and/or OTC use with FDA Cleared TENS and NMES class II devices.

5. Indications for Use

The Neurological Therapy Devices - Accessories including Garment electrodes, which are intended to be used with legally marketed electrical stimulating devices such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The cutaneous electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. The Garment electrodes including glove, socks, sleeve, knee belt and back belt which are made up of silver or conductive silicone rubber.

6. Technical and Performance

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

Element of Comparison	Subject Device	Primary Predicate (K203158)	Reference Predicate (K171798)	Reference Predicate (K171721)	Differences
510(K)	K232995	K203158	K171798	K171721	Same
Company	Shenzhen Roundwhale Technology Co., Ltd.	BioWave Corporation	SilverWear USA,LLC.	Shenzhen Konmed Technology, Co. LTD.	--
Device Name	Neurological Therapy Devices - Accessories	BioWave BioWraps	SilverPro	Electrodes with Silver Conductive	--
Regulation Number	882.1320	882.1320	882.1320	882.1320	Same
Product Code	GXY	GXY	GXY	GXY	Same
OTC / Rx	OTC and Rx	OTC and Rx	OTC	OTC	Same as K203158
Intended Use / Indications for Use	The Neurological Therapy Devices - Accessories including Garment electrodes and Adhesive electrodes, which are intended to be used with legally marketed electrical stimulating devices such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The cutaneous electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. The Garment electrodes including glove, socks, sleeve, knee belt and back belt which are made up of silver or conductive silicone rubber.	The BioWave BioWraps are cutaneous electrodes to be used with legally marketed BioWave branded neurostimulators. The knitted garment electrodes are non-sterile reusable prescription-use and OTC conductive garments that are intended to deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts include hands/wrist, elbow, foot/ankle, knee, and lower back.	The Silverwear SilverPro Series Conductive Garments are cutaneous electrodes to be used with legally marketed TENS or NMES devices. The knitted garment electrodes are non-sterile reusable OTC conductive garments that are intended to deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts can include hand (glove), wrist (sleeve), elbow or arm (sleeve), knee or leg (sleeve), knee high	Electrodes with silver conductive as Glove style, Socks style, Wristbands Style, Wrist sleeve, Elbow Pads Style and Knee Pads Style, Elbow Sleeve, are intended for use with legally marketed TENS stimulating device. The electrodes with silver conductive will deliver stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts can include such as hands (gloves), feet (socks), wrist, elbow and knee.	Same

Element of Comparison	Subject Device	Primary Predicate (K203158)	Reference Predicate (K171798)	Reference Predicate (K171721)	Differences
			stockings, ankle(sleeve), back band, and shoulder band.		
Design (Shape)	Wrappable bands for the hand/wrist, elbow, foot/ankle, knee, and lower back	Wrappable bands for the hand/wrist, elbow, foot/ankle, knee, and lower back	Electrode A: Glove Style Electrode B: Wrist Sleeve Electrode C: Elbow/Arm Sleeve Electrode D: Knee/Leg Sleeve Electrode E: Knee High Socks Electrode F: Ankle Sleeve Electrode G: Back Band Electrode H: Shoulder Band	KM-406: Glove Style KM-407: Socks Style KM-408: Wristbands Style KM-409: Elbow pads Style KM-410: knee Pads Style	Same as K203158
Size	180*120±5mm 210*130±5mm 230*85±5mm 300*100±5mm 1100*150±10mm 1300*180±10mm	All BioWraps are available in small/medium (S/M) and large/extra- large (L/XL) sizes: Low Back: - S/M: 28-38” Waist - L/XL: 38-50” Waist Knee: - S/M: 12-15.5” Waist	Information not publicly available	Gloves KM-406: 200 cm2 Socks KM-407: 285 cm2 Wristbands KM-408: 95 cm2 Elbow pads KM-409: 160 cm2 Knee Pads KM-410: 236 cm2	Similar Impedance parameters less than 7 ohms resistance/inch

Element of Comparison	Subject Device	Primary Predicate (K203158)	Reference Predicate (K171798)	Reference Predicate (K171721)	Differences
	550*220±10mm 1000*125±10mm 520*200±10mm 220*180±10mm 850*650±10mm 550*350±10mm 550*220±10mm	circumference around the kneecap - L/XL: 15.5 - 19” circumference around the kneecap Foot/Ankle: S/M:Women’s shoe 6-9,men’s shoe size 7-8.5 L/XL:Women’s shoe size 9.5-11,men’s shoe size 9-13 Elbow: -S/M:8-12” Circumference around the elbow joint with arm extended -L/XL:12-16” Circumference around the elbow joint with arm extended Hand/wrist: -S/M:6-9” circumference around the dominant hand -L/XL:9-12” Circumference around the dominant hand			
Impedance Parameters	7 ohms resistance/inch	1.27 ohms resistance per inch	7 ohms resistance/inch	2 ohms resistance/inch	Same as K171798

Element of Comparison	Subject Device	Primary Predicate (K203158)	Reference Predicate (K171798)	Reference Predicate (K171721)	Differences
Washable / Not Washable	Washable	Washable	Washable	Washable	Same
Reusable	Single Patient, Reusable	Single Patient, Reusable	Single Patient, Reusable	Single Patient, Reusable	Same
Biocompatibility	Compliant with ISO 10993-5/ -10/-23	Compliant with ISO 10993-5 and -10	Compliant with ISO 10993-5 and -10	Compliant with ISO 10993-5 and -10	same
Patient Contacting Materials	silver fiber, silicone rubber	Silver Fiber	Silver-coated Nylon	Silver-coated Nylon	Similar, Pass the biocompatibility test

Analysis for the differences:

The subject devices are a garment cutaneous electrodes medical devices that have the same or similar design features, construction, indication, intended use, conductivity, electrical connection and target population as the legally marketed predicate devices. The subject devices have similar technological characteristics as the predicate devices. Both the subject and the predicate devices receive electrostimulation signals from legally marketed TENS devices through a standard electrical connection of an electrode which is wired to the TENS device. Both the subject and the predicate devices are washable and intended for multiple uses by a single patient with intact skin.

The subject electrodes are made from conductive silver fiber or conductive silicone rubber and is highly conductive and provides less than 7 ohms resistance per inch which is similar or less than the predicate devices. The actual devices which are fabricated into multiple different garment forms and is connected to a TENS device which is the source of the current that is delivered by the garment electrodes to the target skin tissue. The subject devices are non- sterile multiple use devices which are washable using conventional detergents. Bench tests of the fabric show that the garment electrodes do not change their inherent conductivity with multiple washings so that there is no significant adverse effect on the conductivity of the device or its inherent ability to deliver treatment uniformly to the skin of the wearer even after multiple washings. The biocompatibility testing demonstrates the material is acceptable in comparison to the predicates for the intended use.

The subject devices, Neurological Therapy Devices - Accessories, were demonstrated to be substantially equivalent to the predicate and reference devices cited in the table above with respect to indications, design, materials, function, availability (i.e., over-the-counter use), and/or performance.

Conclusion:

The Neurological Therapy Devices - Accessories have been found to be substantially equivalent to the previously cleared predicate device, BioWave BioWraps(K203158),and the included reference predicates, SilverPro Garment Electrodes (K171798) and Electrodes with Silver Conductive (K171721) , with respect to indications, design, materials, function, availability, and performance.

7. 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:

7.1 Biocompatibility testing

The biocompatibility evaluation for the Neurological Therapy Devices - Accessories conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. Neurological Therapy Devices - Accessories will have direct contact with human body only at intact skin,And the testing included the following tests:

- Cytotoxicity -ISO 10993-5:2009
- Skin Sensitization -ISO 10993-23:2021
- Skin Irritation -ISO 10993-10:2021

7.2 Performance testing

Bench testing has been conducted on the fabric used to fabricate the various forms of the Neurological Therapy Devices - Accessories to demonstrate that that the fabric and the devices meet design controls in terms of conductivity and resistivity, and uniform delivery of low doses of current all consistent with that of the predicate devices. Resistivity testing was conducted using standard industry testing to confirm that the resistivity met the standards of less than 7 ohms per inch through multiple washings to confirm the multiple use aspects of the device.

8. Clinical data:

No clinical testing was performed.

9. Conclusions:

The subject device has the Same intended use and Similar characteristics as the predicate device, Meanwhile, performance testing, bench testing, and Biocompatibility testing 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 Neurological Therapy Devices - Accessories 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.