



January 19, 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: K222252

Trade/Device Name: Self-adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 19, 2022
Received: December 19, 2022

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <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 Physical Medicine 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

510(k) Number (if known)
K222252

Device Name
Self-adhesive Electrode

Indications for Use (Describe)

Self-Adhesive Electrode is intended for use as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF or IFC (Interferential current) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current, for OTC (Over-The-Counter) or Prescription use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Department of Health and Human
 Services Centre of Device and
 Radiological Health Office of Device
 Evaluation
 Traditional 510(k) section

510(K) SUMMARY

as required by section 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:	12/8/2022

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:	12/8/2022

2. Proposed Device and code:

Device Trade Name:	Self-Adhesive Electrode
Model Series	Self-Adhesive Electrode with lead wire; Self-Adhesive Electrode with Snap/Magnetic connector;
Regulation Medical Specialty	Neurology

Product Code:	GXY
Regulation number	21 CFR 882.1320
Device Class	II
510(k)	K222252

3. Predicate Device:

510(K)	Trade Name	Submitter	Product Code
K180865	ZMI Self-adhesive	ZMI Electronics, Ltd.	GXY
K160138	Adhesive Electrodes	GMDASZ Manufacturing Co., Ltd	GXY

4. Description of Proposed Device:

Self-Adhesive Electrode are composed of conductive carbon film and adhesive Electrodes composed of Aluminum foil film, Adhesive Electrodes manufactured by Roundwhale are multi-layer reusable, flexible structures composed of laminated materials commonly used in this application:

No.	Description	Material Composition
1	Top layer	Fabric/Foam/ Tan fabric
2	Middle layer	Conductive film (Silver coated Carbon Film/Carbon film/Aluminum foil film)
3	Bottom layer	Biocompatible self-adhesive conductive hydrogel
4	Connection	Leadwire/snap button/magnetic button
5	double sides adhesive tape	Which is used for attaching the non-woven fabrics and conducting film
6	Release film	Release film is a protective layer for the hydrogel.

The electrodes are designed for single-patient/multiple application use. Because of the adhesive nature of the biocompatible conductive hydrogel, no securing materials are required to secure the device to the patient's skin.

For the electrical connection, Roundwhale provides lead wire type and snap button/Magnetic button type:

- Leadwire assembly:

The electrode is connected to the electrical stimulator by lead wire, at least 40 mm long wire with a standard connector: 0.08"/0.1"(2mm/2.5mm) diameter female socket connector with insulating outer. By design, the insulated outer jacket prevents the conductive connection to earth or hazardous voltages. The lead wire assembly is in compliance with the requirements of FDA performance standard 21 CFR part 898 by testing under ANSI/AAMI ES60601-1, subclause 8.5.2.3.

- Snap button/Magnetic button assembly:

With 2.5~5mm diameter male socket. The snap button and the magnetic button provide different types of physical contact with the source of stimulation current via spring tension or magnetic force among male and female connectors. Either method is similar to the lead wire connection providing the friction to create the physical contact.

5. Indications for Use

Self-Adhesive Electrode is intended for use as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS

(Electrical Muscular Stimulation), IF or IFC (Interferential current) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current, for OTC (Over-The-Counter) or Prescription use.

6. Technical and Performance

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

Comparison to predicate device 1#:

Element of Comparison	Subject Device	Predicate Device	Comment
510(k)	K222252	K180865	N/A
Company	Shenzhen Roundwhale Technology Co., Ltd.	ZMI Electronics, Ltd.	N/A
Device Name	Self-adhesive Electrode	ZMI Self-adhesive Electrodes	N/A
Model name	<ul style="list-style-type: none"> ● Self-adhesive Electrode with leadwire; ● Self-adhesive Electrode with Snap /Magnetic connector; 	SAE Type	N/A
Shape	<ul style="list-style-type: none"> ● Round(50±0.5mm), ● Rectangular(50*30±0.5mm), ● Square(50*50±0.5mm,40*40±0.5mm), ● Oval(40*80±0.5mm) 	<ul style="list-style-type: none"> ● Round, Rectangular, Square, Oval, and Butterfly 	similar 1#
Color	White	White, Red, Black, and Tan	similar 4#
Regulation Number	882.1320	882.1320	Same
Product Code	GXY	GXY	Same
Classification Name	Cutaneous electrode	Cutaneous electrode	Same
Indications for Use	Self-Adhesive Electrode is intended for use as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e.TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF or IFC(Interferential current) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current, for OTC (Over-The-Counter) or Prescription use.	ZMI Self-adhesive Electrodes are intended for as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current, for OTC (Over-The-Counter) or Prescription use.	SE
OTC or Prescription	OTC and Prescription	OTC and Prescription	Same
Target Population	General [Adult]	General [Adult]	Same

Design Feature	Six layers: 1. Insulation backing material: Fabric/Foam/ Tan fabric 2. Conductive film: Aluminum foil film /Carbon film/Carbon film coated with silver/ 3. Conductive hydrogel 4. Connection 5. double sides adhesive tape 6. Release liner	Three layers: 1. Insulation backing material: Fabric/Foam/ Tan fabric 2. Conductive film: Aluminum foil film/Carbon film/Carbon film coated with silver/ 3. Conductive hydrogel	similar 2#
Electrical Connection	Leadwire Snap button Magnetic button	Leadwire Snap button Magnetic button	Same
Lead Wire connector	.080"/0.1"(2mm/2.5mm) female socket or Pin connector	.080" (2mm) female socket connector	similar 3#
Non-sterile	Non-sterile	Non-sterile	Same
Reusable	Reusable	Reusable	Same
Packaging	Re-sealable bag packed	Re-sealable bag packed	Same
Adhesive Type	Self-adhesive	Self-adhesive	Same
Biocompatibility	Complies with ISO10993	Complies with ISO10993	Same
adhesion testing (peel strength)	$\geq 7N$	$\geq 7N$	Same
A.C. Impedance	<300 ohms	<200 ohms	similar 6#
Force required to remove wire from electrode	More than 6 pounds of force	More than 6 pounds of force	Same
Single Patient Use	Yes	Yes	Same

Comparison to predicate device 2#:

Element of comparison	Subject Device	Predicate Device	Comment
510(K) No.	K222252	K160138	NA
Company	Shenzhen Roundwhale Technology Co., Ltd.	GMDASZ Manufacturing Co., Ltd.	N/A
Device Name	Self-adhesive Electrode	Adhesive Electrodes	N/A
Model Name	<ul style="list-style-type: none"> ● Self-adhesive Electrode with leadwire ● Self-adhesive Electrode with Snap 	OCWN1005, OCWN1007, OCWN2505, OCWN2509, OACWN1005, OACWN1007,	N/A

	/Magnetic connector:	OACWN2505, OACWN2509	
● Shape	<ul style="list-style-type: none"> ● Round(50±0.5mm), ● Rectangular(50*30±0.5mm), ● Square(50*50±0.5mm,40*40±0.5mm), ● Oval(40*80±0.5mm) 	Round and Rectangular	similar 1#
Color	White	Tan	similar 4#
Regulation Number	882.1320	882.1320	Same
Product Code	GXY	GXY	Same
Classification Name	Cutaneous electrode	Cutaneous electrode	Same
Indications for Use	Self-Adhesive Electrode is intended for use as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e.TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF or IFC(Interferential current) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current, for OTC (Over-The-Counter) or Prescription use.	The adhesive electrodes are intended for as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF(Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current, for OTC (Over-The-Counter) or Prescription use.	Same
OTC or Prescription	OTC and Prescription	OTC and Prescription	Same
Target Population	General [Adult]	General [Adult]	Same
Design Feature	Six layers: 1. Insulation backing material: Fabric/Foam/ Tan fabric 2. Conductive film: Aluminum foil film /Carbon film/Carbon film coated with silver/ 3. Conductive hydrogel 4.Connection 5.double sides adhesive tape 6.Release liner	Three layers: 1. Insulation backing material: Fabric/Foam/Tan fabric 2. Conductive film: Carbon film/Carbon film coated with silver/Aluminum foil film 3. Conductive hydrogel	Similar 2#
Electrical Connection	Leadwire, Snap button, Magnetic button	Leadwire	Similar 5#
Lead Wire connector	Leadwire connector .080"-0.1" (2mm-2.5mm) female socket or Pin connector with insulating outer jacket.	Leadwire connector .080" (2mm) female socket connector	similar
Non-sterile	Non-sterile	Non-sterile	Same
Reusable	Reusable	Reusable	Same

Packaging	Re-sealable bag packed	Re-sealable bag packed	Same
Self-adhesive	Self-adhesive	Self-adhesive	Same
Biocompatibility	Complies with ISO10993	Complies with ISO10993	Same
adhesion testing (peel strength)	$\geq 7N$	$\geq 7N$	Same
A.C. Impedance	<300 ohms	<300 ohms	Same
Force required to remove wire from electrode	More than 6 pounds of force	More than 6 pounds of force	Same
Single Patient Use	Yes	Yes	Same

Comparison in Detail(s):

1# The shape and size are related to the treatment area. Smaller area may cause higher current density, which leads to discomfort and burns. The current densities for any shaped electrodes exceeding 2mA r.m.s/cm² may require the special attention of the user.

4#: Top fabric color that makes no direct contact with the human body is mainly for identification and marketing purpose, the subject device will be provided in white only, and that no color additives are to be used. and does not raise any new concerns of safety or effectiveness.

2# The subject device and predicate device are similar in construction. They both contain three basic components: a non-conductive top layer, a patient contacting layer, a carbon dispersion pad middle layer, and; while the Self-Adhesive Electrode also contains three additional layer: conductive carbon fiber lead wire (or snap for Magnetic Style Electrode), double sides adhesive tape which is used for attaching the non-woven fabrics and conducting film, and plastic film is a protective layer for the hydrogel. Which the differences will not effect the safety and effectiveness of the Self-Adhesive Electrode.

3# and 5#: The snap button and the magnetic button provide different types of physical contact with the source of stimulation current via spring tension or magnetic force among male and female connectors. Either method is similar to the lead wire connection providing the friction to create the physical contact.

6#: A.C. impedance is different from K180865, but identical to K160138, The difference does not raise any new safety and effectiveness questions and complies with the same performance and safety requirements.

7. Performance Testing:

Test Summary:

To establish substantial equivalence to the identified predicate devices, we performed the following tests on the subject device, Adhesive Electrodes TS 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 biocompatibility evaluation for the Self-Adhesive Electrode 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. Self-Adhesive Electrodes 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, calculated on the basis of 30 minutes each time, ,Expected to is expected once a day, The device is intended to be used for a total duration of 30 days maximum, irrespective of the number of uses or replacement of an individual device with a new one. cumulative sum of single, multiple or repeated contact time is likely to exceed 24 h but not exceed 30 d. And the testing included the following tests:

According to the product manual,

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

7.3 Safety and EMC

To verify the basic safety and essential performance of the subject device, we performed the test noted below:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

The submitted sample(s) complied with the requirements of ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], C1.8.5.2.3

7.4 Bench Testing

Bench tests were conducted on Self-Adhesive Electrode to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

1. Electrical & Impedance Tests: Neutral Electrode (NE) contact impedance

The Self-Adhesive Electrode was tested to assure the current is equally distributed. The Self-Adhesive Electrode was also tested for Impedance to assure proper electrical connection to the skin.

The submitted sample(s) complied with the requirements of IEC 60601-2-2:2017 section 201.15.101.6

2. NE adhesion: (a) Pull test b) Conformability test

The Self-Adhesive Electrode was tested for initial adhesion force and adhesion force after using multiple times.

The submitted sample(s) complied with the requirements of IEC 60601-2-2:2017 section 201.15.101.7

3. Connector & Mechanical tests

The Self-Adhesive Electrode has a Snap or magnetic surface with the purpose to clamp the Self-Adhesive Electrode. This connection was tested to assure multiple use and also to assure the TENS stay fixed to the Self-Adhesive Electrode during use.

4. Packaging tests

Real-Time Shelf Life Test Report

The Self-Adhesive Electrode was tested for storage conditions:

- The Self-Adhesive Electrode should not be stored at temperatures lower than 41°F(+5°C) or higher than 80.6°F (+27°C).

5. Accelerated Aging

The Self-Adhesive Electrode was tested for accelerated aging in worst storage condition to assure within the expiration date the electrode function as expected.

- ASTM F1980 (Reapproved 2016), Standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility)

8. Conclusions:

The proposed device has the same Indications for 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 different questions of safety or effectiveness. Roundwhale Ltd. maintains that the Self-Adhesive Electrode 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.