October 6, 2021

Voncare Medical Device Co., Ltd
% Charles Mack
Principal Engineer
IRC
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K212191
Trade/Device Name: Adhesive Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: July 10, 2021
Received: July 12, 2021

Dear Charles Mack:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K212191

Device Name
Adhesive Electrodes

Indications for Use *(Describe)*
The Adhesive Electrodes are 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 (Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current. The electrode is 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.

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510(k) Summary

Device 510k number: K212191
Preparation Date: October 6, 2021

Submitter Information:
Voncare Medical Device Co., Ltd
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Boluo County, Huizhou City, Guangdong Province, China 516127
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Contact person: Mr. Jimmy Zhai (General Manager)

Corresponding Official:
Charles Mack
Telephone number: 931-625-4938

FDA Registration Number:
Owner/Operator Number: 10047792
Establishment Registration Number: 3011307234

Regulatory Information:
Trade name: Adhesive Electrodes
Common Name: Reusable Neurostimulation Electrodes
Classification Name: Electrodes, cutaneous
Regulation Number: 882.1320 Product Code: GXY
Classification: Class II

Predicate Device:
K160138 GMDASZ Adhesive Electrodes (GMDASZ Manufacturing Co., Ltd.)

Device Description:

Adhesive Electrodes are composed of non-woven fabric, carbon film coated with silver and conductive hydrogel; It is identical in technological characteristics compared to the predicate device, Adhesive Electrodes, OACWN serial cleared in K160138 and the subject devices are also to be sold for over-the-counter (OTC) use and prescription use, which is the same as the predicate device.

Adhesive Electrodes manufactured by Voncare Medical Device Co., Ltd are multi-layer reusable, flexible structures composed of laminated materials commonly used in this application.

First layer: Insulating backing material-nonwoven coated with 30-50um bio-compatible medical adhesive tape
Second layer: Conductive film
Third layer: Bio-compatible self-adhesive conductive hydrogel, thickness 1.0+/-0.2mm
Protective silicon liner: PET
The electrodes are designed for single-patient/multiple application use. Because of the biocompatible conductive hydrogel's adhesive nature, no securing materials are required to secure the device to the patient's skin. The electrode is connected to the electrical stimulator by lead wire, with a standard .080" female socket connector. By design, the insulated outer jacket prevents the conductive connection to earth or hazardous voltages. Wire assembly complies with FDA performance standard 21 CFR Part 898.

Indications for Use:

The Adhesive Electrodes are 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 (Interferential), or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current. The electrode is for OTC (Over-The-Counter) or Prescription use.

Comparison to predicate device:

Characteristics	Subject Device	Predicate Device	Difference Discussion
510K Applicant	Voncare Medical Device Co., Ltd	GMDASZ Manufacturing Co., Ltd.	-
510(K) Number	N/A	K160138	-
Device Name	Adhesive Electrodes	Adhesive Electrodes	-
Model	TS0020/TS0030/TS0050/TS5050/ TS5089/TS50130	OACWN1005/OACWN1007/OAC WN2505/ OACWN2509	-
Regulation Number	882.1320	882.1320	Identical
Product Code	GXY	GXY	Identical
Classification Name	Cutaneous electrode	Cutaneous electrode	Identical
OTC or Prescription	OTC & Prescription	OTC & Prescription	Identical
Medical Specialty	Neurology	Neurology	Identical
Intended Use	The Adhesive Electrodes are 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 (Interferential), or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current. The electrode is for OTC (Over-The-Counter) or Prescription use.	The Adhesive Electrodes are 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 (Interferential), or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current. The electrode is for OTC (Over-The-Counter) or Prescription use.	Identical

Characteristics	Subject Device	Predicate Device	Difference Discussion
Design Feature	Three layers: 1 insulating backing material: non-woven fabric 2 Conductive film: Carbon film coated with silver/Aluminum foil film 3 Conductive hydrogel (VG100)	Three layers: 1. Insulation backing material: Fabric/Foam/Tan fabric 2. Conductive film: Carbon film coated with silver/Aluminum foil film 3. Conductive hydrogel (A, T, or U gel)	1. Same 2. Same 3. The material of conductive hydrogel is different. The difference does not raise any new safety and effectiveness questions and complies with the same biocompatible, performance, and safety requirements.
Electrical Connection	Leadwire	Leadwire	Identical
Protective Liner	PET	PET	Identical
Lead Wire connector	Leadwire connector .080” female socket connector	Leadwire connector .080” female socket connector	Identical
Reusable	Reusable	Reusable	Identical
Packaging	Re-sealable bag packed	Re-sealable bag packed	Identical
Self-adhesive	Self-adhesive	Self-adhesive	Identical
Biocompatibility	Complies with ISO10993	Complies with ISO10993	Identical

Characteristics	Subject Device	Predicate Device	Difference Discussion
A.C. Impedance	<200 ohms A.C. Impedance of Pair electrode	<300 ohms	The difference does not raise any new safety and effectiveness questions and complies with the same performance and safety requirements.
Force required to remove the wire from the electrode	More than 7 pounds of force	More than 6 pounds of force	The difference does not raise any new questions of safety and effectiveness which meet the design requirement
Sterility Status	Non-sterile	Non-sterile	Identical
Single Patient Use	Single Patient Use	Single Patient Use	Identical

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.

Non-Clinical Study:
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:

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 and C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

The test result shows the device complies with the standard's requirements.

Performance Data:
To verify the performance of the subject device, we conducted the tests noted below:

- Adhesion Test
- Pair AC Impedance and Current Dispersion Test
- Retention Test
- Reusability and stability test
- Storability Test (Shelf Life)
- EC12 Disposable ECG electrodes
- EC53 ECG Cables and Leadwire

The test results demonstrate the device meets the requirements.

Biocompatibility

According to ISO10993-1 Fourth edition, 2009-10-15 Annex A Table A.1 - Evaluation tests for consideration, the subject device is classified as:

Surface Device → Contact Intact Skin → Limited Contact Duration(:524h)

We conducted the applicable tests noted below:

Cytotoxicity Tests (ISO10993-5)

Skin Irritation Test (ISO10993-10)

Skin Sensitization Test (ISO10993-10)

The test result shows it complies with the requirement.

Sterility Information

Not applicable, the subject device is not sterile.

Clinical Study:

No clinical study is included in this submission.

Conclusion:

The submitted new Adhesive Electrodes have the same intended use and similar technological characteristics as the predicate devices. Moreover, the information contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the submitted adhesive electrodes are substantially equivalent to the predicate devices.

END