DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 11, 2016

GMDASZ Manufacturing Co., Ltd
% Charles Mack
Principal Engineer
IRC
2250 Duportail Street, M275
Richland, Washington 99352

Re: K160138
Trade/Device Name: Adhesive Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: June 28, 2016
Received: July 13, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160138

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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510k Summary

Device 510k number: K160138

Submitter Information:
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Contact person: Mr. Xiangjie Zhang (General Manager)

FDA Registration Number:
Owner/Operator Number: 10031210
Establishment Registration Number: 3008197884

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 Devices:

K092546	GMDASZ TENS Electrodes	(GMDASZ Manufacturing Co., Ltd.)
K132998	Wandy self-adhesive electrodes	(WANDY Rubber Industrial Co., Ltd.)

Device Description:
Adhesive Electrodes are composed of conductive carbon film, and carbon film coated with silver are identical in technological characteristics compared to our own previous 510K cleared electrodes in K092546, so this premarket notification supports a change to the product labeling only to allow the product to be sold for over-the-counter (OTC) use and prescription use.

Adhesive Electrodes composed of Aluminum foil film, are technologically equivalent to the predicate devices - K132998 Wandy self-adhesive electrodes for over-the-counter (OTC) use and prescription use.

Adhesive Electrodes manufactured by GMDASZ are multi-layer reusable, flexible structures composed of laminated materials commonly used in this application:

First layer: Insulating backing material: Fabric/foam/tan fabric
Second layer: Conductive film: Carbon film/Carbon film coated with silver/Aluminum foil film
Third layer: Biocompatible self-adhesive conductive hydrogel
Protective liner: PET

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. The electrode is connected to the electrical stimulator by lead wire, with a standard .080" recessed female terminal with insulating outer jacket. By design, the insulated outer jacket prevents the conductive connection to earth or hazardous voltages. Wire assembly is incompliance 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:

Element of comparison	Subject Device (K160138)	Predicate Device (K092546)	Justification
Company	GMDASZ Manufacturing Co., Ltd.	GMDASZ Manufacturing Co., Ltd.	Same
Device Name	Adhesive Electrodes	GMDASZ TENS Electrodes	N/A
Model Name	OCWN1005, OCWN1007, OCWN2505, OCWN2509, OACWN1005, OACWN1007, OACWN2505, OACWN2509	CWN1005, CWN1007, CWN2505, CWN2509, ACWN1005, ACWN1007, ACWN2505, ACWN2509	N/A
Regulation Number	882.1320	882.1320	Same
Product Code	GXY	GXY	Same
Classification Name	Cutaneous electrode	Cutaneous electrode	Same
OTC or Prescription	OTC and Prescription	Prescription	Predicate device K132998 (below) is both OTC and Rx only. Additionally, the labeling has defined restricted areas of application, exactly like the predicate device K132998.

Intended 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. The electrode is for OTC (Over-The-Counter) or Prescription use.	The GMDASZ TENS Electrodes are intended for use as a reusable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. GMDASZ's reusable electrodes are designed and intended to be used with marketed, Electrical Stimulators i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation). The electrotherapy electrodes are intended to be used to apply electrical stimulation current to the patient's skin.	Similar
Design Feature	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 (A, T or U gel)	Three layers: 1. Insulating backing material: Fabric/Foam/Tan fabric 2. Conductive plastic film: Carbon film/ Carbon film coated with silver 3. Conductive hydrogel (A, T or U gel)	1) Same 2) Same except subject device has the option of an Aluminum foil film. The Aluminum foil film is used as a conductive film in predicate K132998 (below). 3) Same
Electrical Connection	Leadwire	Leadwire	Same
Protective Liner	PET	PET	Same
Lead Wire connector	Leadwire connector .080" female socket connector	Leadwire connector .080" female socket connector	Same
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
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	Single Patient Use	Single Patient Use	Same

Element of comparison	**Subject Device (K160138)**	**Predicate Device (K132998)**	**Comment**
Company	GMDASZ Manufacturing Co., Ltd.	Wandy Rubber Industrial Co. Ltd	N/A
Device Name	Adhesive Electrodes	Wandy Self-adhesive electrodes	N/A
Model name	LWN1005, LWN1007, LWN2505, LWN2509	Type A, Type P, Type M	N/A
Regulation Number	882.1320	882.1320	Same
Product Code	GXY	GXY	Same
Classification Name	Cutaneous electrode	Cutaneous electrode	Same
Intended 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. The electrode is for OTC (Over-The-Counter) or Prescription use.	Wandy Self-adhesive Electrode is intended to transmit electrical current to patient skin for TENS (Transcutaneous Electrical Nerve-Stimulation) and EMS (Electrical muscular Stimulation) application, for OTC (Over-the-Counter) or Prescription use. The electrodes are used for adults only.	Similar

OTC or Prescription	OTC and Prescription	OTC and Prescription	Same
Design Feature	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 (A, T or U gel)	Three layers: 1. Insulating backing material: Woven Fabric/Foam 2. Conductor: Aluminum/Carbon 3. Conductive hydrogel (A, T or U gel)	1) Doesn't impact safety and effectiveness of subject device 2) Subject device contains aluminum foil as a conductive film. Predicate includes 'Type A' model which has used aluminum foil as a conductive device 3) Same
Electrical Connection	Leadwire	Leadwire or Snap	Similar Subject device does not have snap style connection but this shouldn't impact its safety or effectiveness.
Protective Liner	PET	PET	Same
Lead Wire connector	Leadwire connector .080" female socket connector	Leadwire connector .080" female socket connector	Same
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

A.C. Impedance	<300 ohms	<200 ohms	Similar Although subject device has slightly higher impedance, it is still <2kohm and should not affect safety and effectiveness of subject device
Force required to remove wire from electrode	More than 6 pounds of force	More than 6 pounds of force	Same
OTC or Prescription	OTC and Prescription	OTC and Prescription	Same
Single Patient Use	Single Patient Use	Single Patient Use	Same

Performance:

The Adhesive Electrodes are composed of conductive carbon film, and carbon film coated with silver. They are identical to GMDASZ's previous 510K cleared electrodes in K092546 This submission supports a change only to allow the product to be sold for Over-The-Counter (OTC) use. The electrodes are compared to the Wandy Rubber Industrial Co., Ltd. Self-adhesive electrodes, K132998. The mechanical and electrical properties of the submitted GMDASZ electrodes are the same as the Wandy Self-adhesive electrodes.

For Adhesive Electrodes composed of Aluminum foil film, all the materials are same as the previously cleared electrodes in K092546 except the conductive media, so no new biocompatibility tests were conducted. To verify the safety and performance of it, GMDASZ conducted new tests. These tests are the same as our previous cleared prescription electrode in K092546, including safety test, adhesion test, current dispersion test, retention test, reusability and stability test as well as some performance test by refer to EC12/EC53. The test result shows the new electrodes with aluminum foil film is identical to the both the GMDASZ and Wandy predicate devices in safety and performance characteristics.

Clinical:

No clinical tests were needed.

Conclusion:

The submitted new Adhesive Electrodes have the same intended use and similar technological characteristics as the predicate devices. Moreover, 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.