June 28, 2018

ZMI Electronics, Ltd.
Yuta Lee
President
6F-1, 286-4, Shin Ya Road
Kaohsiung, 806 TW

Re: K180865
Trade/Device Name: ZMI Self-Adhesive Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: February 23, 2018
Received: April 2, 2018

Dear Yuta Lee:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2018.06.28 13:45:12 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180865

Device Name
ZMI Self-Adhesive Electrodes

Indications for Use *(Describe)*
ZMI Self-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 electrodes are 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: K180865

Submitter Information

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Contact person: Wayne Chen, Sales Manager
Date: June 6, 2018

FDA Registration Number

Owner/Operator Number: 9035676
Establishment Registration Number: 9617486

Regulatory Information

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

Predicate Devices:

K132998 Wandy self-adhesive electrodes (WANDY Rubber Industrial Co., Ltd.) *Primary Predicate
K160138 Adhesive Electrodes (GMDASZ Manufacturing Co., Ltd.)

Device Description

ZMI Self-adhesive electrodes provide a means for establishing electrical contact between the lead connected to a TENS, EMS or NMES stimulation device and the skin, and are multi-layer, reusable, flexible structures composed of laminated materials commonly used in the application:

Top layer: Insulation material: Fabric/foam/tan fabric
Middle layer: Conductive film (Silver coated Carbon Film/Carbon film/Aluminum foil film)
Bottom layer: Biocompatible self-adhesive conductive hydrogel
Connection: Leadwire/snap button/magnetic button

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.

Indications for Use

ZMI Self-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 electrodes are for OTC (Over-The-Counter) or Prescription use.

Comparison to predicate device:

Element of Comparison	Subject Device (K180865)	Predicate Device (K132998)	Comment
Company	ZMI Electronics, Ltd.	Wandy Rubber Industrial Co. Ltd	N/A
Device Name	ZMI Self-adhesive electrodes	Wandy Self-adhesive electrodes	N/A
Model name	SAE Type	Type A, Type P, Type M	N/A
Shape	Round, Rectangular, Square, Oval, and Butterfly	Round, Rectangular, Square, Oval, and Butterfly	Same
Color	White, Red, Black, and Tan	White, Red, Black, and Tan	Same
Regulation Number	882.1320	882.1320	Same
Product Code	GXY	GXY	Same
Classification Name	Cutaneous electrode	Cutaneous electrode	Same
Intended 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.	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.	SE
OTC or Prescription	OTC and Prescription	OTC and Prescription	Same
Target Population	General [Adult]	General [Adult]	Same
Design Feature	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	Three layers: 1. Insulation backing material: Woven Fabric/Foam 2. Conductive film: Aluminum foil film /Carbon film/Carbon film coated with silver/ 3. Conductive hydrogel	1. SE The fabric and foam are commonly used for insulation cover on adhesive electrodes. The fabric material includes the synthetic fibers and natural fibers. Both fiber types can fulfill the insulation property, which won't raise any concerns of safety or effectiveness. 2. Same 3. Same
Electrical Connection	Leadwire Snap button Magnetic button	Leadwire Snap button	Same Same SE The magnetic button provides another type of physical contact with the

			source of stimulation current via magnetic force among male and female connectors. This is similar to the other connection methods like leadwires & snap buttons. No new concerns of safety or effectiveness are raised.
Lead Wire connector	Leadwire connector .080" (2mm) female socket connector	Leadwire connector .080" (2mm) 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
Adhesive Type	Self-adhesive	Self-adhesive	Same
Biocompatibility	Complies with ISO10993	Complies with ISO10993	Same
A.C. Impedance	<200 ohms	<200 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 to predicate device:

Element of comparison	Subject Device (K180865)	Predicate Device (K160138)	Justification
Company	ZMI Electronics, Ltd.	GMDASZ Manufacturing Co., Ltd.	N/A
Device Name	ZMI Self-adhesive electrodes	Adhesive Electrodes	N/A
Model Name	SAE Type	OCWN1005, OCWN1007, OCWN2505, OCWN2509, OACWN1005, OACWN1007, OACWN2505, OACWN2509	N/A
Shape	Round, Rectangular, Square, Oval, and Butterfly	Round and Rectangular	SE 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 /cm^2 may require the special attention of the user. The color is mainly for identification and marketing purpose, and does not raise any new concerns of safety or effectiveness.
Color	White, Red, Black, and Tan	Tan	

Regulation Number	882.1320	882.1320	Same
Product Code	GXY	GXY	Same
Classification Name	Cutaneous electrode	Cutaneous electrode	Same
Intended 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.	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	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	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	Same
Electrical Connection	Leadwire Snap button Magnetic button	Leadwire	SE 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.
Lead Wire connector	Leadwire connector .080" (2mm) female socket connector	Leadwire connector .080" (2mm) 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	<200 ohms	<300 ohms	SE
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

Performance

ZMI self-adhesive electrodes are composed of insulation fabric, conductive carbon film, and conductive hydrogel. Electrical performance was evaluated by measuring the AC impedance and current dispersion across the surface of the electrodes. Adhesive performance was evaluated by performing a repeated skin adhesion test. Electrode stability was evaluated by assessing electrical performance under normal use conditions. The electrode material should be reliable to resist physical and chemical breakdown as a result of conducting electrical current. To assess this, ZMI self-adhesive electrodes were tested to ensure they fulfilled the specifications after a period of the conventional use. No shelf-life testing was conducted. As the storage conditions could affect the shelf-life, it is recommended to always keep electrodes cool and dry, and to avoid exposure of the surface to heat and humidity. The electrical and mechanical properties of the connectors were evaluated by measuring the resistance of the connection and the connection retention force.

The subject device has a magnetic button for electrical connection, which differs from the two predicate devices. The conventional method of electrical connection of adhesive electrodes is to use either a snap button or lead wire to provide physical contact with the source of stimulation current via the spring tension or the friction between male and female connectors. The method of the magnetic button applies similar concepts, providing physical contact with the source of stimulation current via magnetic force among male and female connectors. The new technological characteristic of the subject device with the magnetic button is identical to the legally marketed device under K172876.

Biocompatibility

Biocompatibility evaluation for ZMI self-adhesive electrodes was done according FDA Good Manufacturing Practice & ISO 10993-1. The following tests were identified and done:

- Cytotoxicity
- Irritation
- Sensitization

Clinical

No clinical tests were needed.

Conclusion

Verification testing of the ZMI self-adhesive electrode included electrical and mechanical tests to show that it meets its target specifications over a range of operating and storage conditions. Verification and performance testing further demonstrated that it meets user needs as reflected in the functional specification.

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