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

March 8, 2016

Shenzhen Mailuokang Technology Co., Ltd.
% Ms. Elena Lu
Senior Consultant
Shenzhen Joyantech Consulting Co., Ltd.
Room 2032, International Mayors Communication Centre
Shenzhen, Guangdong, 518000
China

Re: K152815
Trade/Device Name: Mailuokang Self-adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 28, 2016
Received: February 4, 2016

Dear Ms. Lu:

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)*
K152815

Device Name
Mailuokang Self-adhesive Electrode

Indications for Use *(Describe)*
Mailuokang Self-adhesive Electrode is intended for use as reusable, conductive adhesive interface between the patient's skin and the electrical stimulation devices. Example electrical stimulation devices for current applications of the electrodes includes, but are not limited to, TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscle Stimulation). Mailuokang Self-adhesive Electrode is for prescription use and over-the-counter use, for single patient use only.

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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted as required by requirements of SMDA and 21 CFR §807.92.

Administrative Information

Date of Summary prepared	Sep., 21, 2015
Manufacturer information	Company title: Shenzhen Mailuokang Technology Co., Ltd. Company address: Rm 602, 6/F, Building B, Nanchang Jianyu No.2 Industrial Zone, Gushu Village, Xixiang Street, Baoan District, Shenzhen, China Phone: +86-755-8525 8460 Fax: +86-755-8525 8461 Contact Person: Mr. Pandeng. Hu E-mail: 1962807321@qq.com
Submission Correspondent 卓远天成	Shenzhen Joyantech Consulting Co., Ltd. Address: Room 2032, International Mayors Communication Centre, No. 55 Shizhou middle road , Nanshan District, Shenzhen Contact person: Ms. Elena. Lu; Mr. Field. Fu E-Mail: elena@cefda.com; cefda13485@163.com
Establishment registration number	

Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Mailuokang Self-adhesive Electrode
Model:	Lead Wire Style Electrode, Snap Style Electrode
Classification name:	Electrode, cutaneous
Review Panel:	Neurology

Product Code:	GXY
Device Class:	II
Regulation Number:	882.1320

Predicate Device Information

Sponsor:	Phoenix Medical Devices, LLC
Device:	THERATRODE
510(K) Number:	K112312

Device Description

Mailuokang Self-adhesive Electrode is used as a reusable and re-positionable transcutaneous electrical nerve stimulation electrode in conjunction with an electrical stimulator for TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscle Stimulation). Mailuokang Self-adhesive Electrode is for prescription use and over-the-counter use, for single patient use only.

Intended Use

Mailuokang Self-adhesive Electrode is intended for use as reusable, conductive adhesive interface between the patient's skin and the electrical stimulation devices. Example of electrical stimulation devices for current applications of the electrodes includes, but are not limited to, TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscle Stimulation). Mailuokang Self-adhesive Electrode is for prescription use and over-the-counter use, for single patient use only.

Technological characteristics of the subject device compared to the predicate device

The subject device and the predicate device have the same intended use, similar technological characteristics, and similar material composition. 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 subject device is substantially equivalent to the predicate device.

The detailed substantially equivalent table is shown as follows:

Items	Predicate Device(K112312)	Subject Device	Comparison
General Characteristics			
Indications for Use	To conduct electrical stimulation from commercially available nerve stimulation devices to the patient's skin. Single patient use - re-usable. Self adhering and re-positionable. Over the counter use.	Mailuokang Self-adhesive Electrode is intended for use as reusable, conductive adhesive interface between the patient's skin and the electrical stimulation devices. Example electrical stimulation devices for current applications of the electrodes includes, but are not limited to, TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscle Stimulation). Mailuokang Self-adhesive Electrode is for prescription use and over-the-counter use, for single patient use only.	Substantially Equivalent (**Note 01**)
OTC or Prescription	OTC Use	Prescription use and Over-the-Counter use	Substantially Equivalent (**Note 02**)
Classification Name	Cutaneous Electrode	Cutaneous Electrode	Same
Product Code	GXY 882.1320	GXY 882.1320	Same
Device Class	Class II	Class II	Same
Reusable	Yes	Yes	Same
Single patient Use	Yes	Yes	Same
Multiple Applications	Yes	Yes	Same
Sterility Status	Non-sterile	Non-sterile	Same
Technical Characteristics			
Design Features	Four basic components: * A patient contacting layer of hydrogel material	Six basic components for Lead Wire Style Electrode: • non-woven fabrics;	Substantially Equivalent (**Note 03**)

Items	Predicate Device(K112312)	Subject Device	Comparison
	which has been tested and found to be bio-compatible with humans and provides both the electrically conductive medium necessary to aid in the transmission of electrical current to the patient plus the adhesive properties necessary to maintain sufficient contact with the patient's skin; * A carbon dispersion pad middle layer that evenly distributes the electrical current across the surface of the electrode; * A non-conductive top layer of various materials such as spun lace (fabric), polyethylene or polypropylene foam or other similar materials that form a protective and flexible top layer to the electrode * A wire or conductive carbon fiber lead wire which is glued to the assembly of the middle and top layer and terminates in a .080" (2mm) female connector common to the electrotherapy industry and which mates with the plurality of commercially available nerve stimulation devices on the market today.	• double sides adhesive tape; • conducting film; • hydrogel; • plastic film; • carbon fiber wire. Six basic components for Snap Style Electrode: • non-woven fabrics; • double sides adhesive tape • conducting film; • hydrogel; • plastic film and • snap.	
Hydrogel Composition	Unknown	Glyrol, Polyacrylic acid, Water and Salt.	Substantially Equivalent (**Note 04**)
Biocompatibility	Theratrode's hydrogel has passed three biocompatibility tests: skin	Mailuokang's hydrogel has passed three biocompatibility tests: skin	Same

Items	Predicate Device(K112312)	Subject Device	Comparison
	irritation, cytotoxicity and delayed contact sensitization	irritation, sensitization and cytotoxicity	
Performance test	Measuring the electrical conductivity (inverse of impedance)	Measuring the electrode contact impedance and adhesion	Substantially Equivalent (**Note 05**)
Conductive Surface Shapes	Various shapes(square, round, rectangular, oval)	Various shapes (rectangular, oval, circle)	Substantially Equivalent (**Note 06**)
Electrode Impedance	Unknown	The average value of 10-hertz (Hz) impedance for 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (μA) peak-to-peak (p-p), shall not exceed 2 kilohms (kΩ). None of the individual pair impedances shall exceed 3 kΩ.	Substantially Equivalent (**Note 07**)

Discussion about the similarities and differences between the subject device and the predicate device:

Note 01:

The only difference between the subject device and the predicate device are the wordings.

Note 02:

The differences are: the subject device is for prescription use and over-the-counter use while the predicate device is only for OTC use. However, many cutaneous electrodes intended for use with transcutaneous electrical nerve stimulators have been cleared by the FDA for prescription use, e.g., the Axelgaard ValuTrode Neurostimulation Electrodes (K970246), Jiajian Self- adhesive Electrode (K090198). Thus the intended use of the subject device and predicate device are substantially equivalent.

Note 03:

The subject device and predicate device are similar in construction. They both contain four basic components: a non-conductive top layer, a patient contacting layer, a carbon dispersion pad middle layer (similar function for conducting film of Mailuokang Lead Wire

Style and Snap Style electrode,) and conductive carbon fiber lead wire (or snap for Snap Style Electrode); while the Mailuokang electrode also contains two additional layer: 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 Mailuokang Self-adhesive Electrode.

Note 04:

Though the hydrogel composition of the predicate device is unknown, the Mailuokang's hydrogel composition is the same with Electrode pads of GYMFORM ABS&CORE Electrode (K142055) which has been cleared by the FDA. What's more, Mailuokang's electrode and the predicate device's electrode both passed three biocompatibility tests: skin irritation, cytotoxicity and delayed contact sensitization.

Note 05:

Although the subject device and the predicate device conducting different electrical performance tests, they are both used to demonstrate the same performance of the electrode: good conductivity. For the predicate device, the electrical conductivity (inverse of impedance) is measured, while for the subject device, the electrode contact impedance is measured. Many cutaneous electrodes intended for use with transcutaneous electrical nerve stimulators have been cleared by the FDA by passing impedance testing, e.g., SOF-PACH^{TM} Reusable Neurostimulation Electrodes (K020735), Jiajian Self- adhesive Electrode (K090198). Because the Mailuokang Self-adhesive Electrode has the same intended use and fundamental technology as these other electrodes, it is substantially equivalent to them. Moreover, the subject device also considered the adhesion performance. The subject device has passed self-evaluation tests for impedance and adhesiveness. Thus, the performance of subject device is substantially equivalent to the predicate device.

Note 06:

The differences in shapes will not effect the safety and effectiveness of the Mailuokang Self-adhesive Electrode.

Note 07:

Although electrode impedance of the predicate device is unknown, the comparison testing between the predicate device and the subject device was performed according to ANSI/AAMI EC 12:2000/(R)2005 standard, and both the devices passed the testing. Which the

differences will not effect the safety and effectiveness of the Mailuokang Self-adhesive Electrode.

Brief discussion of the nonclinical tests

The Mailuokang Self-adhesive Electrode passed self-evaluation tests for impedance and adhesiveness. Mailuokang's electrode has passed three biocompatibility tests: skin irritation, sensitization and cytotoxicity.

Brief discussion of clinical tests

Not applicable.

Other information (such as required by FDA guidance)

No other information.

Conclusions

The subject device Mailuokang Self-adhesive Electrode is substantially equivalent to THERATRODE whose 510(k) number is K112312.