August 7, 2018

Dong Guan Ou Kang Electronics CO., LTD
% Field Fu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
Room 1122, International Mayors Communication Centre
Shenzhen, 511470 Cn

Re: K181234
Trade/Device Name: Self-adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: May 9, 2018
Received: May 9, 2018

Dear Field Fu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Michael J. Hoffmann -S

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)*
k181234

Device Name
Self-adhesive electrode

Indications for Use *(Describe)*
Self-adhesive electrode is intended for single use, conductive adhesive interface between the patient's skin and the electrical stimulation devices. Some common types of the stimulation devices include, but are not limit to, TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The electrode is for OTC (Over-The -Counter) or Prescription 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.

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510(k) Summary

Date of summary prepared: 08/06/2018

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

1. Administrative Information

Date of summary prepared	
Manufacturer information	Company title: Dong Guan Ou Kang Electronics CO.,LTD Company address: 3rd floor, Xiqunli building, Shipai road, Yanwo village, Shipai town, Dongguan Phone: +86-0769-82686009 Fax: +86-0769-82686009 Contact person: Nianjun Liu E-mail: nianjun_liu@sohu.com
Submission Correspondent	Name: Shenzhen Joyantech Consulting Co., Ltd Address: Room 1122, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen Contact person: Field Fu; Summer Wu; Elly Xv E-mail: summer@cefda.com; elly@cefda.com

2. Device information

Type of 510(k) submission:	Traditional
Trade name:	Self-adhesive electrode
Model:	Lead wire type electrode and snap type electrode
Classification Name:	Electrode, Cutaneous
Review panel:	Neurology
Product Code:	GXY
Device Class	II
Regulation number:	882.1320

3. Predicate Device Information

Sponsor:	Shenzhen Mailuokang Technology Co., Ltd.
Device:	Mailuokang Self-adhesive Electrode
510(k) number:	K152815

4. Device description

1) Intended use/indications for use

Self-adhesive electrode is intended for single use, conductive adhesive interface between the patient's skin and the electrical stimulation devices. Some common types of the stimulation devices include, but are not limit to, TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The electrode is for OTC (Over-The -Counter) or Prescription use, for single patient use only.

2) Device specification

The specification of self-adhesive electrode is listed below.

Model	Shape	Product Size(mm)	Connector Size (hole diameter) (mm)
Non-woven lead wire type electrode	Rectangular and circular	Rectangular: 40×40;40×60;50×50;50×60;50×70;50×90;50×100;60×80;60×90;70×110;90×130 Circular: Φ30；Φ40；Φ50；Φ80	2.0, 2.5
Non-woven snap type electrode	Rectangular, circular, oval and hand shape	Rectangular: 40×40; 40×80; 50×50; 50×90; 50×100; 60×90 Circular: Φ30；Φ40；Φ50；Φ80 Oval: 43×30 Hand shape: 75×46	3.3, 3.6

3) Device design

Non-woven lead wire type electrode and non-woven snap type electrode have different appearance and construction. See Figure 1 and Figure 2 for the structure picture of non-woven lead wire type electrode and non-woven snap type electrode.

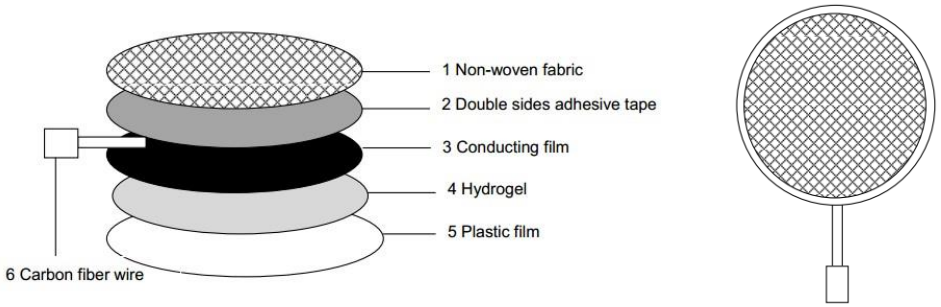

Figure 1 The structure of non-woven lead wire type electrode

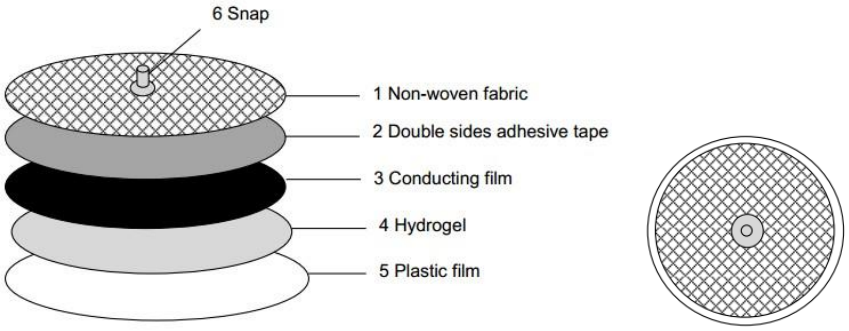

Figure 2 The structure of non-woven snap type electrode

4) Materials used

Both non-woven lead wire type electrode and snap type electrode are composed of a non-woven fabric, a double side adhesive tape, conducting film, hydrogel and plastic film. The construction difference between non-woven lead wire electrode and non-woven snap electrode is lead wire and snap.

5) Physical and performance characteristics of the device

Electrical impedance: less than 3KΩ.
Current uniformity: the current deviation index of the electrode is less than 5%.
Adhesive performance: 30 minutes maximum duration use.

6) Principle of Operation

Self-adhesive electrode functions as a passive device by carrying an electrical signal from a stimulation device through the device cable and electrode lead wire or snap to the user skin. Electrical signal from an electrical stimulator is conducted to the self-adhesive electrode through a lead wire or snap; which is dispersed across the conductive film, then transmitted through the conductive adhesive hydrogel to the surface of the patient's skin.

7) Material of construction

Component	Material
Non-woven fabric	100% polypropylene in white
Conducting film	Carbon paste
Hydrogel	Cross linked acrylic resin, polyhydric alcohol, electrolytic salt, additives and de-ionized water
Lead wire	PVC
Snap	Nickel-clad copper

5. Technological characteristics of the subject device compared to the predicate device

Items	Predicate Device (K152815)	Subject Device	Comparison
General Characteristics			

Items	Predicate Device (K152815)	Subject Device	Comparison
Classification Name	Cutaneous Electrode	Cutaneous Electrode	Same.
Product Code	GXY	GXY	Same.
Regulation Number	882.1320	882.1320	Same.
Device Class	Class II	Class II	Same.
Intended Use/Indications for 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.	Self-adhesive electrode is intended for use as single use, conductive adhesive interface between the patient's skin and the electrical stimulation devices. Some common types of the stimulation devices include, but are not limit to, TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The electrode is for OTC (Over-The-Counter) or Prescription use, for single patient use only.	Similar. (Note 1)
Intended User/Patient Population	No specified population.	No specified population.	Same.
Electrical Connection	Lead wire or snap.	Lead wire or snap.	Same.
OTC or prescription use	OTC use and prescription use.	OTC use and prescription use.	Same.

Items	Predicate Device (K152815)	Subject Device	Comparison
Reusable	Yes	No.	Similar. (Note 1)
Single Patient Use	Yes	Yes	Same.
Multiple Applications	Yes	No.	Similar. (Note 1)
Sterility Status	Non-sterile	Non-sterile	Same.
Technical Characteristics			
Electrode dimensions(cm)	For lead wire style electrode: Rectangular: 3×7;4×4;5×5;5×6;5×7;6×9;8×12;8×13 For snap style electrode: Rectangular: 9×4 Circle: Φ4；Φ5；Φ8.5 Oval: 4.5×3	For non-woven lead-wire type electrode: Rectangular: 4×4;4×6;5×5;5×6;5×7;5×9;5×10;6×8;6×9;7×11;9×13 Circular: Φ3；Φ4；Φ5；Φ8 For non-woven snap type electrode: Rectangular: 4×4; 4×8; 5×5; 5×9; 5×10; 6×9 Circular: Φ3；Φ4；Φ5；Φ8 Oval: 4.3×3 Hand shape: 7.5×4.6	Similar. (Note 2)
Conductive surface area(cm^2)	12.56~104	7~117	Similar. (Note 2)
Design Features	Six basic components for Lead Wire Style Electrode: • non-woven fabrics; • double sides adhesive tape; • conducting film; • hydrogel; • plastic film;	Six basic components for Lead Wire Style Electrode: • non-woven fabrics; • double sides adhesive tape; • conducting film; • hydrogel; • plastic film;	Same.

<table>
<tr><th>Items</th><th>Predicate Device (K152815)</th><th>Subject Device</th><th>Comparison</th></tr>
<tr><td></td><td>• carbon fiber wire.
Six basic components for Snap Style Electrode:
• non-woven fabrics;
• double sides adhesive tape;
• conducting film;
• hydrogel;
• plastic film;
• snap.</td><td>• carbon fiber wire.
Six basic components for Snap Style Electrode:
• non-woven fabrics;
• double sides adhesive tape;
• conducting film;
• hydrogel;
• plastic film;
• snap.</td><td></td></tr>
<tr><td>Hydrogel Composition</td><td>Glyrol, Polyacrylic acid, Water and Salt</td><td>Crosslinked acrylic resin, polyhydric alcohol, electrolytic salt, additives and de-iconized water.</td><td>Similar.
(Note ~~1~~3)</td></tr>
<tr><td>Function and concentration of each ingredient in final formulation</td><td>Not publicly available.</td><td>
<table>
<tr><th>Ingredient</th><th>Concentration (WT%)</th><th>Function</th></tr>
<tr><td>Crosslinked acrylic resin</td><td>15-25</td><td>Cross-linking polymerization.</td></tr>
<tr><td>polyhydric alcohol</td><td>40-60</td><td>Buffer and humactant.</td></tr>
<tr><td>electrolytic salt</td><td>2-10</td><td>Ionic conducting media.</td></tr>
<tr><td>additives</td><td><0.5</td><td>Stabilization.</td></tr>
<tr><td>de-iconized water</td><td>20-40</td><td>Solution.</td></tr>
</table>
</td><td>Note 3</td></tr>
</table>

Items	Predicate Device (K152815)	Subject Device	Comparison
pH of hydrogel	Not publicly available.	6.5~7.5	Note 4
Conductivity of hydrogel (S/m)	Not publicly available.	50	Note 5
Resistivity (Ωm)	Not publicly available.	0.02	Note 5
Volume of hydrogel (cm^3)	Not publicly available.	The volume of hydrogel varies by the shape of electrodes, ranging from 0.7 to 11.7.	Note 6
Maximum duration of use	30min.	30min.	Same.
Biocompatibility	Mailuokang's hydrogel has passed three biocompatibility tests: skin irritation, sensitization and cytotoxicity.	Self adhesive electrode has passed 3 biocompatibility tests: skin irritation, sensitization and cytotoxicity.	Same.
Performance Test	Measuring the electrode contact impedance and adhesion.	Size, electrical impedance and adhesion.	Same.
Conductive Surface Shapes	Various shapes (rectangular, oval, circle)	Various shapes (rectangular, oval, circular, hand shape)	Similar. (Note 2)

Discussion of the similarities and differences:

Note 1:
The difference between the subject device and the predicate device is that, the predicate device is intended for multiple uses, while the subject device is intended for single use. The difference does not adversely affect the safety and effectiveness of the device.

Note 2:
The electrode dimension and conductive surface of the predicate device is similar to the subject device. The difference does not adversely affect the safety and effectiveness of the device.

Note 3:
Both Mailuokang self-adhesive electrode and self-adhesive electrode have passed the biocompatibility test, electrode impedance test and adhesion test.
Therefore, the difference in hydrogel composition will not raise any safety or efficacy issues.

Note 4:
The conductive gel is called hydrogel, it is pre-applied to the electrode. The hydrogel pH of the predicate device is unknown, as the subject device has pass the biocompatibility tests performed per ISO 10993 series standards, the difference does not adversely affect the safety and effectiveness of the device.

Note 5:
The conductivity and impedance of the hydrogel in the predicate device is unknown. As both the electrical impedance of the predicate device and the subject device are less than 3kΩ, the difference does not adversely affect the safety and effectiveness of the device.

Note 6:

The difference in volume of hydrogel does not adversely affect the safety and effectiveness of the device.

6. Brief discussion of the nonclinical tests

Self-adhesive electrode has passed performance tests for size, electrical impedance, current uniformity test and adhesion. Adhesion test is performed according to IEC 60601-2-2:2009 Clause 201.15.101.7.

Self-adhesive electrode has passed 3 biocompatibility tests: cytotoxicity, skin irritation and.skin sensitization. The biocompatibility tests are performed according to ISO 10993-1, 5 and 10.

The shelf life of self-adhesive electrode is verified according to ASTM F 1980-07.

7. Brief discussion of clinical tests

Not applicable.

8. Other information (such as required by FDA guidance)

No other information.

9. Conclusions

The subject device is substantially equivalent to Mailuokang Self-adhesive Electrode whose 510(k) number is K152815.