March 26, 2019

Hong Qiangxing (Shen Zhen) Electronics Limited
% Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903, No. 19 Dongbao Road, Songjiang Area
Shanghai, 201613 China

Re: K183154
Trade/Device Name: SM Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: March 8, 2019
Received: March 21, 2019

Dear Doris Dong:

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,

Vivek J. Pinto -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)*
K183154

Device Name
SM Electrodes

Indications for Use *(Describe)*
SM Electrodes are intended to transmit electrical current to patient skin for use with transcutaneous 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.

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

[As required by 21 CFR 807.92]

**1. Submission Information:**

| | |
|---|---|
| 510(k) Number: | K183154 |
| Date: | March 26, 2019 |
| Type of 510(k) Submission: | Traditional |
| Basis for 510(k) Submission: | New device |
| Submitter/Manufacturer: | Hong Qiangxing(Shen Zhen) Electronics Limited<br>4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126 |
| Contactor: | Doris Dong (Consultant)<br>Shanghai CV Technology Co., Ltd.<br>Rm. 903, No. 19 Dongbao Rd., Songjiang Area, Shanghai, 201613 China<br>E-mail: doris_d@126.com<br>Tel: 86 21-31261348 |

**2. Device Description:**

| | |
|---|---|
| Proprietary Name: | SM Electrodes |
| Common Name: | Cutaneous electrode |
| Classification Name: | Cutaneous electrode |
| Product Code: | GXY |
| Device Class: | II |
| Regulation Number: | 21 CFR 882.1320 |
| Review Panel: | Neurology |
| Indications for use: | SM Electrodes are intended to transmit electrical current to patient skin for use with transcutaneous 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. |
| Device Description: | SM Electrode pad is used as an accessory to the TENS or EMS device unit, which transmits electrical current to patient skin. The electrical current of electrode pad is first transmitted via the snap button then transmitted to the conductive gel which is adhered to patient skin.<br><br>SM Electrode Pad is composed of a top cover material, connector snap button, conductive carbon film, conductive hydrogel media, and a carrier line.<br><br>It is non-sterile and intended for single adult patient multiple application use. The SM Electrode has various shapes and sizes.<br><br>To connect with a nerve or muscle stimulator, this SM Electrode Pad has male snap button. The electrical pad connecting two separated gels together through a non-woven fabric has a pair of male snap button and the diameter is 3mm. The electrical pad with only one male snap button are to |

be used in pairs and the diameter of snap button is 4mm.

When not in use, the hydrogel face is covered by a PET(polyethylene terephthalate) carrier line.

**3. Predicate Device Identification**

K152648--Ennova Self-adhesive Electrode--January 12, 2016
K182111--DL Adhesive Electrode--January 17, 2019

**4. Non-Clinical Test Conclusion**

Bench tests were conducted on SM Electrodes to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:
- Shelf life testing per ASTM F1980:2016.
- ANSI AAMI ISO 10993-5:2009/(R) 2014, Biological evaluation of medical devices -- Part 5: Tests for In Vitro Cytotoxicity. (Biocompatibility)
- ISO 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for Irritation and Skin Sensitization. (Biocompatibility)
- ANSI AAMI IEC 60601-2-2:2009, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Contact Impedance test per 201.15.101.6
Adhesion test per 201.15.101.7

**5. Substantial Equivalent Based on Assessment of Clinical Performance Data:**

Clinical data was not including in this submission.

**6. Substantially Equivalent Comparison Conclusion**

| | **New Device** | **Predicate Device 1** | **Predicate Device 2** |
|---|---|---|---|
| 501(k) number | K183154 | K152648 | K182111 |
| Trade Name: | SM Electrodes | Ennova Self-adhesive Electrode | DL Adhesive Electrode |
| Common Name: | Cutaneous electrode | Cutaneous electrode | Cutaneous electrode |
| Classification Name: | Cutaneous electrode | Cutaneous electrode | Cutaneous electrode |
| Product Code: | GXY | GXY | GXY |
| Regulation Number: | 882.1320 | 882.1320 | 882.1320 |
| Medical Specialty: | Neurology | Neurology | Neurology |
| Device Class: | II | II | II |
| Indications for use: | SM Electrodes are intended to transmit electrical current to patient skin for use with transcutaneous electrical | Ennova Self-adhesive Electrode is intended to transmit electrical current to patient skin for use with transcutaneous electrical | DL Adhesive Electrode is intended to transmit electrical current to patient skin for use with transcutaneous electrical |

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|---|---|---|---|---|---|---|
| | 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. | | 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. | | stimulation devices. Some common types of the stimulation devices include, but are not limited to **TENS** (Transcutaneous Electrical Nerve Stimulation) and **EMS** (Electrical Muscular Stimulation). The electrode is for **OTC** (Over-The -Counter) or Prescription use. | |
| Target population: | Single patient use and multiple application | | Single patient use and multiple application | | Single patient use and multiple application | |
| Prescription use | OTC and Prescription use | | OTC and Prescription use | | OTC and Prescription use | |
| Design (shape & connection): | Round, rectangle, butterfly, oval, according to customized specification.<br>Snap button with male snap connector | | Round, rectangle, oval, butterfly according to customized specification.<br>Lead wire with female socket, or snap button with male snap connector | | Round, rectangle, butterfly, oval, according to customized specification.<br>Lead wire with female socket, or snap button with male snap connector | |
| Materials: | - Top cover material<br>- Electrically conductive carbon cloth<br>- Biocompatible conductive hydrogel<br>- Electrode carrier liner | | - Top cover material<br>- Electrically conductive carbon cloth<br>- Biocompatible conductive hydrogel<br>- Electrode carrier liner | | - Top cover material<br>- Electrically conductive carbon cloth<br>- Biocompatible conductive hydrogel<br>- Electrode carrier liner | |
| Electrode Pad Size | Round | Min.Ø20mm; Max.Ø70mm | Round | Min.Ø32mm; Max.Ø70mm | Round | Min.Ø18mm; Max.Ø85mm |
| | Rectangle | Min.50×50mm; Max.170×100mm | Rectangle | Min.40×40mm; Max.100×130mm | Rectangle | Min.40×40mm; Max.40×350mm |
| | Oval | Min.43×30mm; Max.120×76mm | Oval | Min.50×120mm; Max.100×240mm | Oval | 50×78mm |
| | Butterfly | 165×79mm | Butterfly | Min.55×75mm; Max.95×165mm | Butterfly | Min.93×150mm; Max.110×150mm |
| Connector retention force | | | | | | |
| --Lead wire with female socket | NA | | 10.80N | | 10.85N | |
| --snap button with male snap connector | 9.62N | | 9.60N | | 9.61N | |
| Hydrogel thickness | 1.0mm ± 0.2mm | | 1.0mm ± 0.2mm | | 1.0mm ± 0.2mm | |
| Standards met: | 1. Impedance test, Conformability test and Fluid | | 1. Lead wires test per 8.5.2.3 of AAMI/ANSI ES 60601-1; | | 1.Lead wires test per8.5.2.3 of AAMI/ANSI ES 60601-1; | |

| | | | |
|---|---|---|---|
| | tolerance test per 201.15.101.6 and 201.15.101.7 of ANSI AAMI IEC 60601-2-2:2009;<br>2. Impedance Test (Dispersion Test) per FDA requirement;<br>3. Peel strength test according to manufacturer's requirement;<br>4. Shelf life test per ASTM F1980:2016; | 2. Impedance test, Conformability test and Fluid tolerance test per 201.15.101.6 and 201.15.101.7 of IEC 60601-2-2:2009<br>3. Impedance Test (Dispersion Test) per FDA requirement;<br>4. Peel strength test according to manufacturer's requirement;<br>5. Shelf life test per ASTM F1980:2011; | 2.Impedance test, Conformability test and Fluid tolerance test per 201.15.101.6 and 201.15.101.7 of ANSI AAMI IEC 60601-2-2:2017<br>3.Impedance Test (Dispersion Test) per FDA requirement;<br>4.Peel strength test according to manufacturer's requirement；<br>5.Shelf life test per ASTM F1980:2016; |
| Biocompatibility | ISO10993-5:2009;<br>ISO10993-10:2010 | ISO10993-5:2009;<br>ISO10993-10:2010 | ISO10993-5:2009;<br>ISO10993-10:2010 |
| Sterility Status: | Non-sterile | Non-sterile | Non-sterile |
| Electrical safety | NA | Lead wire meets Clause 8.5.2.3 of AAMI/ANSI ES60601-1 | Lead wire meets Clause 8.5.2.3 of AAMI/ANSI ES60601-1 |
| Other Performance | Good electrical conductivity, good adhesive property | Good electrical conductivity, good adhesive property | Good electrical conductivity, good adhesive property |

**The Conclusions:**

Based on the successful biocompatibility testing, electrode current distribution test results, SM Electrodes are safe and effective when used as an interface between a user's skin and an approved nerve and muscle stimulation device. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed devices identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.