January 17, 2019

Shaoxing DL Healthcare Co., Ltd.
% Doris Dong
Manager
Shanghai CV Technology Co., Ltd
Room 903, No. 19 Dongbao Road, Songjiang Area
Shanghai, 201613 Cn

Re: K182111
Trade/Device Name: DL Self-adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 12, 2018
Received: October 22, 2018

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)*
K182111

Device Name
DL Adhesive Electrode

Indications for Use *(Describe)*
DL Adhesive Electrode is 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 limited 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.

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Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K182111
Date:	January 17, 2019
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	SHAOXING DL HEALTHCARE CO., LTD JIUJIN LAND, BAIGUAN STREET, SHANGYU DISTRICT, SHAOXING CITY, ZHEJIANG PROVINCE, CHINA, 312300
Contactor:	Doris Dong (Consultant) Shanghai CV Technology Co., Ltd. Room 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris_d@126.com Tel: 86 21-31261348

2. Device Description:

Proprietary Name:	DL Adhesive Electrode
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:	DL Adhesive Electrode is 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 limited to **TENS** (Transcutaneous Electrical Nerve Stimulation) and **EMS** (Electrical Muscular Stimulation). The electrode is for **OTC** (Over-The-Counter) or Prescription use.
Device Description:	DL Adhesive Electrode 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 or lead wire then transmitted to the conductive gel which is adhered to patient skin. DL Adhesive Electrode is composed of a top cover, connector snap button or lead wire, conductive carbon film, conductive hydrogel media, and a carrier liner. The carrier liner is made of PET (polyethylene terephthalate) or LDPE(Low Density Polyethylene). DL Adhesive Electrode is non-sterile and intended for single adult patient multiple application use. The Adhesive Electrode has various shapes and sizes.

To connect with a nerve or muscle stimulator, DL Electrode pads have lead wire type or snap button type. The lead wires have female sockets, while the snap buttons have male connectors. When not in use, the hydrogel face is covered by a PET (polyethylene terephthalate) carrier liner.

The conductive hydrogel is imported from Covidien, USA, we used the same conductive hydrogel as the Self-Adhering TENS/'NMES/FES Stimulating Electrode which was 510(k) cleared with number of K100418. Further, our entire Adhesive Electrode together with the conductive hydrogel media has passed the Biocompatibility test, Shelf life test, Impedance test, Adhesive test, and so on.

3. Predicate Device Identification

K152648--Ennova Self-adhesive Electrode--January 12, 2016
K100418--Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode--September 3, 2010

4. Non-Clinical Test Conclusion

Bench tests were conducted on DL Adhesive Electrode 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:
- ASTM F1980-16, Standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility)
- 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)
- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-2-2 Edition 6.0 2017-03, 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

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

Clinical data was not including in this submission.

6. Substantially Equivalent Comparison Conclusion

*Basic technological characteristics, New device VS. Primary Predicate device:

	New Device	**Predicate Device**
501(k) number	K182111	K152648
Trade Name:	DL Adhesive Electrode	Ennova Self-adhesive Electrode
Common Name:	Cutaneous electrode	Cutaneous electrode
Classification	Cutaneous electrode	Cutaneous electrode

DL Adhesive Electrode;
SHAOXING DL HEALTHCARE CO., LTD

Name:				
Product Code:	GXY		GXY	
Regulation Number:	882.1320		882.1320	
Medical Specialty:	Neurology		Neurology	
Device Class:	II		II	
Indications for use:	DL Adhesive Electrode is 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 limited to **TENS** (Transcutaneous Electrical Nerve Stimulation) and **EMS** (Electrical Muscular Stimulation). The electrode is for **OTC** (Over-The -Counter) or Prescription use.		Ennova Self-adhesive Electrode is 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 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	
Prescription use	OTC and Prescription use		OTC and Prescription use	
Design (shape & connection):	Electrode Pad: Round, rectangle, butterfly, oval, according to customized specification. Lead wire with female socket, or snap button with male snap connector		Round, rectangle, oval, butterfly according to customized specification. Lead wire with female socket, or snap button with male snap connector	
Materials:	- Top cover material - Electrically conductive carbon cloth - Biocompatible conductive hydrogel - Electrode carrier liner		- Top cover material - Electrically conductive carbon cloth - Biocompatible conductive hydrogel - Electrode carrier liner	
Electrode Pad Size	Rectangle	Min.40×40mm; Max.40×350mm	Rectangle	Min.40×40mm;Max.100×130mm
	Butterfly	Min.93×150mm;Max.110×150mm	Butterfly	Min.55×75mm; Max.95×165mm
	Round	Min.Ø18mm; Max.Ø85mm	Round	Min.Ø32mm; Max.Ø70mm
	Oval	50×78mm	Oval	Min.50×120mm; Max.100×240mm
-- Patient contact area of Electrode Pad	Round	Min.254.34mm^2; Max.5671.63mm^2	Round	Min.804mm^2; Max.3846.5mm^2
	Rectangle	Min.1600mm^2; Max.7000mm^2	Rectangle	Min.1600 mm^2; Max.13000mm^2
	Oval	3900mm^2	Oval	Min.4710 mm^2; Max.18840mm^2
	Butterfly	Min.6975mm^2; Max.8250mm^2	Butterfly	Min.4125 mm^2; Max.15675mm^2
--Hydrogel thickness	1.0mm±0.2mm		1.0mm±0.2mm	
--Hydrogel Volume Resistivity	1500 ohm-cm maximum		1500 ohm-cm maximum	
Conductive carbon film	PU, Conductive carbon		PU, Conductive carbon	
Electrode	Round	415~599Ω	Round	397~612Ω

Impedance of Electrode Pad	Rectangle	421~711Ω	Rectangle	432~624Ω
	Oval	437~601Ω	Oval	412~642Ω
	Butterfly	451~688Ω	Butterfly	407~616Ω
Maximum Current for Power Density @ 500 Ohms	Use Jiajian® TENS(K112288) for calculation, the Maximum R.M.S current is 13.7mAr.m.s		Use Jiajian® TENS(K112288) for calculation, the Maximum R.M.S current is 13.7mAr.m.s. Calculation formulas as follow: Maximum Output Voltage: 36V@500Ω Pulse Duration: 60~300μS Waveform: Pulsed Monophasic Frequency: 0.5~120Hz Ir.m.s= $\sqrt{120Hz*\frac{300\mu s}{1000000}}*72mA=$ 13.7 mAr.m.s	
Current Density of Electrode Pad (Use IRMS= 13.7mA for calculation)	Round	Min.0.242mA/cm^2 Max.5.386mA/cm^2	Round	Min.0.36mA/cm^2 Max.1.70mA/cm^2
	Rectangle	Min.0.196mA/cm^2 Max.0.85mA/cm^2	Rectangle	Min.0.11mA/cm^2 Max.0.86mA/cm^2
	Oval	0.351mA/cm^2	Oval	Min.0.07mA/cm^2 Max.0.29mA/cm^2
	Butterfly	Min.0.17mA/cm^2 Max.0.196mA/cm^2	Butterfly	Min.0.09mA/cm^2 Max.0.33mA/cm^2
Maximum Power Density of Electrode Pad (W/cm^2)	Round	0.0369W/cm^2	Round	0.0117W/cm^2
	Rectangle	0.006W/cm^2	Rectangle	0.0059W/cm^2
	Oval	0.0024W/cm^2	Oval	0.002W/cm^2
	Butterfly	0.0013W/cm^2	Butterfly	0.0023W/cm^2
(FDA guidance states that a maximum average power density should be less than 0.25 watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns.)				
Connector retention force				
--Lead wire with female socket	10.85N		10.80N	
--snap button with male snap connector	9.61N		9.60N	
Standards met:	1. Lead wires test per8.5.2.3 of AAMI/ANSI ES 60601-1; 2. Impedance test, Conformability test and Fluid tolerance test per 201.15.101.6 and 201.15.101.7 of ANSI AAMI IEC 60601-2-2:2009; 3. Impedance Test (Dispersion Test) per FDA requirement; 4. Peel strength test according to manufacturer's requirement; 5. Shelf life test per ASTM F1980:2016;		1. Lead wires test per 8.5.2.3 of AAMI/ANSI ES 60601-1; 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 3. Impedance Test (Dispersion Test) per FDA requirement; 4. Peel strength test according to manufacturer's requirement; 5. Shelf life test per ASTM F1980:2011;	
Biocompatibility	ISO10993-5:2009;		ISO10993-5:2009;	

	ISO10993-10:2010	ISO10993-10:2010
Sterility Status:	Non-sterile	Non-sterile
Electrical safety	Lead wire meets Clause 8.5.2.3 of AAMI/ANSI ES60601-1: 2005/(R)2012 And A1:2012	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

*Basic technological characteristics, New device VS. Reference Predicate device (comparison of the subject and predicate hydrogels):

	New Device	**Predicate Device**
510(k) number	K182111	K100418
Trade Name:	DL Adhesive Electrode	Superior Starburst Reusable Self-Adhering TENS/NMES/FES Stimulating Electrode
Common Name:	Cutaneous electrode	Cutaneous electrode
Classification Name:	Cutaneous electrode	Cutaneous electrode
Product Code:	GXY	GXY
Regulation Number:	882.1320	882.1320
Medical Specialty:	Neurology	Neurology
Device Class:	II	II
Indications for use:	DL Adhesive Electrode is 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 limited to **TENS** (Transcutaneous Electrical Nerve Stimulation) and **EMS** (Electrical Muscular Stimulation). The electrode is for **OTC** (Over-The -Counter) or Prescription use.	The proposed Superior Starburst Reusable Self-Adhering TENS/'NMES/FES Stimulating Electrode is intended for over-the-counter use with transcutaneous electrical stimulation devices to provide the conductive interface between the stimulation device and the patient's skin.
Body contact	Intact Skin	Intact Skin
Biocompatibility	Complies with requirements of ISO 10993-1, including: Cytotoxicity (ISO 10993-5), Irritation and Sensitization (ISO 10993-10)	Complies with requirements of ISO 10993-1, including: Cytotoxicity (ISO 10993-5), Irritation and Sensitization (ISO 10993-10)
Sterilization	Provided non-sterile	Provided non-sterile
Shelf life	2 years	3 years
Impedance (at 1 MHz)	1500 ohm-cm maximum	1500 ohm-cm maximum
Stainless Steel Adhesion (180° peel)	136 grams minimum(≈1.3N)	136 grams minimum(≈1.3N)
Gel thickness	1.0mm±0.2mm	35mil(≈0.89mm)
Conductive material	Water (Aqua) with Inorganic Salt	Water (Aqua) with Inorganic Salt
Composition	Water (solvent) Glycerin (polymerization) Polymer (gel forming)	Water (solvent) Glycerin (polymerization) Polymer (gel forming)

	Polyol (gel forming) Amorphous Silica (gel forming) Inorganic Salt (Conductive) Potassium Chloride(enhancer)	Polyol (gel forming) Amorphous Silica (gel forming) Inorganic Salt (Conductive) Potassium Chloride(enhancer)
PH	3.0-3.5	3.0-3.5

The Conclusions:

Based on successful biocompatibility testing of the whole Adhesive Electrode together with the conductive hydrogel, the electrical performance of the insulated lead wire components and electrode current distribution test results, Adhesive Electrode is 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.