May 22, 2018

Shaoxing DongZhi Electrical Technology Co., Ltd.
Haze XU
Quality Manager
Xinsha Village, Cao E Street, Shangyu Area
Shaoxing, Zhejiang 312352 Cn

Re: K180773
Trade/Device Name: Reusable and Self-Adhesive Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: March 14, 2018
Received: March 23, 2018

Dear Haze XU:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K180773

Device Name
Reusable and Self-Adhesive Electrodes

Indications for Use *(Describe)*
This product is an adhesive electrode which is intended for use as the re-usable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. It is intended to be used with legally marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).

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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Section5 510(k) summary

I Submitter

Device submitter: Shaoxing DongZhi Electrical Technology Co.,Ltd
Xinsha Village, Cao E Street, Shangyu Area, Shaoxing City,
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Contact person: Haze XU
Quality Manager
Phone: +86 575 82597860
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II Device

Trade Name of Device: Reusable and Self-Adhesive Electrodes
Common name: Cutaneous Electrode
Classification: Class II, 21 CFR 882.1320
Product Code: GXY

III Predicate Device

Trade name: TENS Electrodes
Common name: Cutaneous Electrode
Classification: Class II, 21 CFR 882.1320
Product Code: GXY
Premarket Notification: K160081
Company name: CATHAY MANUFACTURING CORP.

IV Device description

The Reusable and Self-Adhesive Electrodes are made of conductive hydrogel, fabric cloth and carbon film. They work when sticking to human skin and connecting with electrical stimulators by lead wires. During the treatment, electrical pulses are passed across the intact surface of the skin to activate the underlying nerves.

V Indications for use

This device is an adhesive electrode which is intended for use as the re-usable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. It is intended to be used with legally marketed Electrical Simulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).

VI Comparison of technological characteristics with the predicate devices

The Reusable and Self-Adhesive Electrodes have the same intended use and principle operation, the technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the Reusable and Self-Adhesive Electrodes and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	**Reusable and Self-Adhesive Electrodes (subject device)**	**TENS Electrodes k160081 (predicate device)**	**Discussion**
Intended use	The proposed device is an adhesive electrode which is intended for use as the re-usable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. It is intended to be used with marketed Electrical Simulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).	The proposed device is intended for use as the disposable, conductive adhesive interface between the patient's skin and the electrical stimulator to apply electrical stimulation current, and is intended to be used with marketed electrical stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).It's for OTC use.	Identical
Shapes	Round, Rectangular, Square, Oval, Butterfly	Round, Rectangular, Square, Crescent, Calabash	Substantially equivalent. The shape of the device does not alter its intended use.
Surface area	Round: 2.5cm, 2.8cm, 3.2cm, 4.5cm, 5.0cm, 7.0cm, 7.5cm in diameter: Square: 4.0cm*4.0cm, 4.5cm*4.5cm, 5.0cm*5.0cm; Rectangular: 4.0cm*6.0cm, 4.0cm*8.0cm, 4.0cm*10.0cm, 4.0cm*15.0cm, 4.0cm*35.0cm, 4.5cm*9.5cm, 5.0cm*6.0cm, 5.0cm*9.0cm, 5.0cm*10.0cm, 7.0cm*12.0cm, 7.0cm*13.0cm,7.5cm*10.0cm, 7.5cm*13.0cm, 8.0cm*13.0cm, 10.0cm*20.0cm; Oval: 4.0cm*6.0cm, 5.0cm*10.5cm 5.0cm*13.0cm;	Round: 5cm in diameter; Rectangular: 5cm*10cm, 6cm*10cm; Crescent: 2.4cm*4.2cm; Square: 3.2cm*3.2cm; Calabash: 8.0cm*5.5cm	Substantially equivalent. The surface area of the device does not alter its intended use.

	Butterfly: 9.3cm*15.0cm		
Components	Substrate/Wire/Hydro-gel/Scrim/Conductive Fiber/Carbon conductive film/Liner	Substrate/Wire/Hydro-gel/Scrim/Conductive Fiber/Carbon conductive film/Liner	Identical
Materials	Non-woven Fabric + Adhesive	Non-woven Fabric + Adhesive	Identical
	Wire and Terminal coated PVC	Wire and Terminal coated PVC	Identical
	Hydro-gel	Hydro-gel	Identical
	PET Fabric	PET Fabric	Identical
	Carbon fiber + Reinforcing fiber	Carbon fiber + Reinforcing fiber	Identical
	Poly-isobutylene, Carbon Black, Graphite, Additives	Poly-isobutylene, Carbon Black	Substantially equivalent.
Biocompatibility	Comply with ISO 10993 series	Comply with ISO 10993 series	Identical
Sterility	Non-sterile	Non-sterile	Identical
Re-usable	For single patient	For single patient	Identical
Shelf life	3 years	2 years	Substantially equivalent.

VII Summary of Non-clinical tests:

Compare to primary predicate product specified in K160081, our device and the predicate device are substantially equivalent. The proposed Cutaneous Electrodes are evaluated through Electrode Performance testing (Electrical Impedance Performance, Adhesive Performance, and Tensile Strength), Biocompatibility testing, Stability testing, and Reusability testing.

Biocompatibility testing

Biocompatibility of the electrodes was evaluated in accordance with ISO 10993-1:2009 for the body contact category of “Surface-contacting devices: Skin” with a contact duration of “Limited (< 24 hours)”. The following tests were performed, as recommended: Cytotoxicity, Irritation and Sensitization. All evaluation acceptance criteria were met

VIII Conclusion

The Reusable and Self-Adhesive Electrodes is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.