December 13, 2017

ShenZhen Quality Medical Technology Co.,Ltd
% Jet Li
Regulation Manager
Guangzhou LETA Testing Technology Co., Ltd
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, Guangdong, CN

Re: K171381
Trade/Device Name: Adhesive Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 28, 2017
Received: November 6, 2017

Dear Jet Li:

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)*
K171381

Device Name
Adhesive Electrodes

Indications for Use *(Describe)*
The Adhesive Electrodes are intended to transmit electrical current to patient skin for TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation) applications. It is for OTC (Over-The -Counter) or Prescription use and is to be used for adults 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. **Date of the summary prepared: December 11, 2017**

2. **Submitter's Information**

Sponsor:

510(k) Owner's Name: ShenZhen Quality Medical Technology Co.,Ltd

Establishment Registration Number: N/A

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Application Correspondent:

Guangzhou LETA Testing Technology Co., Ltd.

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Contact Person: Mr. Jet Li

Tile: Regulation Manager

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Email: med-jl@foxmail.com

3. **Subject Device Information**

- Trade Name: Adhesive Electrodes
- Common Name: Cutaneous electrode

- Classification name: Electrode, Cutaneous
- Review Panel: Neurology
- Product Code: GXY
- Regulation Class: II
- Regulation Number: 882.1320

4. Predicate Device Information

Predicate Device 1

Sponsor	Wandy Rubber Industrial Co., Ltd
Device Name	Wandy Self-adhesive Electrodes
510(k) Number	K132998
Product Code	GXY
Regulation Number	882.1320
Regulation Class	2

Predicate Device 2

Sponsor	GMDASZ Manufacturing Co., Ltd
Device Name	Adhesive Electrodes
510(k) Number	K160138
Product Code	GXY
Regulation Number	882.1320
Regulation Class	2

5. Device Description

The Adhesive Electrodes transmit electrical current to patient skin, the electrical current is first transmitted via the snap button then transmitted to the conductive gel which is adhered to patient skin.

Adhesive Electrodes are multi-layer reusable, flexible structures, composed of laminated materials commonly used in this application:

First layer: Insulating backing material: EVA foam
Second layer: Conductive film: Carbon film
Third layer: Biocompatible self-adhesive conductive hydrogel

Protective liner: PET

The dimension of the adhesive electrode is 40 mm (L) × 70 mm (W) ×3mm (H).

6. Intended Use / Indications for Use

The Adhesive Electrodes are intended to transmit electrical current to patient skin for TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation) applications. It is for OTC (Over-The -Counter) or Prescription use and is to be used for adults only.

7. Bench Testing (Non-clinical)

Compare to primary predicate devices specified in K132998 and K160138, our device and the predicate devices are same in, raw materials, physical features, and same manufacturing processes. The biocompatibility performance equivalence evidence of proposed electrode can be demonstrated according to ISO10993-1, ISO10993-5 and ISO10993-10.

The proposed Electrode evaluated through Electrode Performance testing (Electrical Impedance Performance, Adhesive Performance, Current dispersion and Peel force), Biocompatibility testing and Reuse testing.

The non-clinical tests demonstrated that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.

8. Clinical Test Conclusion

No clinical study is needed to be included in this submission.

9. Test Summary

Sensitivity testing criteria as specified in ISO 10993-10 and cytotoxicity testing criteria as specified in ISO 10993-5.
ISO 14971:2007 Medical Device, Harm Control Application to Medical Device
Shelf life testing according to FDA recognized standard ASTM F1980 – 16 (Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices)

10. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Electrode piece is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
Characteristics				
Device Name and Model	Adhesive Electrodes	Wandy Self-adhesive Electrodes	Adhesive Electrodes	--
510 (K) Number	Applying	K132998	K160138	--
Intended Use	The Adhesive Electrodes are intended to transmit electrical current to patient skin for TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation) applications. It is for OTC (Over-The -Counter) or Prescription use and is to be used for adults only.	Wandy Self-adhesive Electrode is intended to transmit electrical current to patient skin for TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation) applications, for OTC (Over-The -Counter) or Prescription use. The Electrode are used for adults only.	The adhesive electrodes are intended for as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current. The electrode is for OTC (Over-The-Counter) or	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
			Prescription use.	
Product Code	GXY	GXY	GXY	SE
Regulation Number	882.1320	882.1320	882.1320	SE
OTC or Prescription	OTC and Prescription	OTC and Prescription	OTC and Prescription	SE
Intended patient population	adults	adults	--	SE
Single Patient Use	Single Patient Use	Single Patient Use	Single Patient Use	SE
Reusable	Reusable	Reusable	Reusable	SE
Design Feature	Three layers: 1. Insulation backing material: EVA foam 2. Conductive film: Carbon film 3.Conductive hydrogel	Three layers: 1. Insulating backing material: Woven Fabric/Foam 2. Conductor: Aluminum/Carbon 3. Conductive hydrogel	Three layers: 1. Insulation backing material: Fabric/Foam/Tan fabric 2. Conductive film: Carbon film/Carbon film coated with silver/Aluminum foil film 3. Conductive hydrogel	SE
Protective Liner	PET	PET	PET	SE
Electrical Connection	Snap button	Snap button or lead wire	Snap button or lead wire	SE
Non-sterile	Non-sterile	Non-sterile	Non-sterile	SE
Reusable	Reusable	Reusable	Reusable	SE
A.C. Impedance	<300 ohms	<300 ohms	<300 ohms	SE
Biocompatibility	All user directly contacting materials are compliance with	All user directly contacting materials are compliance with	Has passed the required skin sensitivity testing	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
	ISO10993-5 and ISO10993-10 requirements.	ISO10993-5 and ISO10993-10 requirements.	criteria as specified in the Tripartite Biocompatibility Guidance for Medical Devices and IS0 10993-1 requirements for skin contact. These tests include Cytotoxicity, Sensitization and Primary Skin Irritation Tests.	

Finial Conclusion:

Based on the indication for use, technology characteristics, and performance testing, the proposed device has been shown to be appropriate for its indication for use and is considered to be substantially equivalent to the primary predicate device and reference device.