DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 25, 2015

Jiangsu Zekang Medical Technology Co., Ltd.
c/o Doris Dong
Manager
Shanghai Cv Technology Co., Ltd
Room 1706, No. 128 Songle Rd., Songjiang Area
Shanghai, 201600
CHINA

Re: K150971/S001
Trade/Device Name: Zekang Self-Adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: July 06, 2015
Received: July 13, 2015

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150971

Device Name
Zekang Self-Adhesive Electrodes

Indications for Use *(Describe)*
Zekang 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.

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:	K150971
Date:	March 15th, 2015
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Jiangsu Zekang Medical Technology Co., Ltd. Building 22, Wuxi Zhongguancun Software Park, Wuxi city, Jiangsu, 214135 China
Contactor:	Doris Dong Shanghai CV Technology Co., Ltd. Room 1706, No. 128 Songle Rd., Songjiang Area, Shanghai, 201600 China E-mail: doris_d@126.com Tel: 86 21-31261348 / Fax: 86 21-37824346

2. Device Description:

Proprietary Name:	Zekang Self-adhesive Electrode
Common Name:	Cutaneous electrode
Classification Name:	Cutaneous electrode
Product Code:	GXY
Device Class:	II
Regulation Number:	882.1320
Review Panel:	Neurology
Indications for use:	Zekang 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 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:	Zekang Self-adhesive Electrode is used as an accessory to the TENS or EMS device unit, which transmits electrical current to patient skin. The electrical current is first transmitted via the lead wire or snap button then transmitted to the conductive gel which is adhered to patient skin. Zekang Self-adhesive Electrode is composed of a cover, connector lead wire or snap button, conductive carbon film, conductive hydrogel, and an electrode carrier liner. It is non-sterile and intended for single adult patient multiple application use. Zekang Self-adhesive Electrode has various shapes and sizes. To connect with a nerve or muscle stimulator, this Electrode has lead wire type and snap button type. For lead wire type electrode, the wire is at least 40mm long, with 2.0~3.5mm diameter female socket. For snap button type

electrode, the connector is male snap button. The individual electrodes are electrically connected in pairs. When not in use, the hydrogel face is covered by a PET (polyethylene terephthalate) release liner.

The conductive hydrogel is imported from Covidien, USA, which was 510(k) cleared with number of K100418. And the whole Zekang Self-adhesive Electrode together with the conductive hydrogel has again passed the Biocompatibility test, Shelf life test, Impedance test, Adhesive test, and so on.

3. Predicate Device Identification

510k number	Device name	Manufacturer	Date cleared
K130987	ValuTrode® Neurostimulation Electrodes	Axelgaard Manufacturing Co., Ltd.	2013
K090198	Jiajian Self-adhesive Electrode	Wuxi Jiajian Medical Instrument Co., Ltd	2009

4. Substantially Equivalent Comparison Conclusion

Detailed comparison data is included in Section 9 of "Substantial Equivalence Discussion" of this 510(k) submission.

	Comparison with K130987	Comparison with K090198
Similarities:	Same intended use, composition, safety performance	Same intended use, composition, safety performance, OTC and Prescription use
Differences:	Zekang Self-adhesive Electrode is for OTC and Prescription use, while ValuTrode® Neurostimulation Electrodes for OTC use only.	Zekang Self-adhesive Electrode has lead wire and snap connection configurations, while Jiajian Self-adhesive Electrode has lead wire type only.
Conclusion:	Based on successful biocompatibility testing of the skin contacting conductive hydrogel, the electrical performance of the insulated lead wire components and electrode current distribution test results, Zekang Self-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.	

5. Non-Clinical Test Conclusion

Bench tests were conducted on Zekang Self-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 (Reapproved 2011), Standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility)
- 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, Medical electrical equipment -- Part 1: General requirements

for basic safety and essential performance

- IEC 60601-2-2 Edition 5.0 2009-02, 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