January 10, 2018

Shenzhen Konmed Technology Co., Ltd
% Cecilia Ceng
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, Guangdong, 510006 China

Re: K171722
Trade/Device Name: Electrodes with snap / Electrodes with pigtail
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 21, 2017
Received: October 30, 2017

Dear Cecilia Ceng:

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)*
K171722

Device Name
Electrodes with snap / Electrodes with pigtail

Indications for Use *(Describe)*
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 legally marketed electrical stimulators, i.e. TENS (Transutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). It's for Over-the-Counter (OTC) 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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Chapter 5. 510(k) Summary

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. Submitter's Information

510(k) Owner's Name: Shenzhen Konmed Technology Co., Ltd
Establishment Registration Number: Applying
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Application Correspondent:

Application Correspondent:
Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
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Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name: Electrodes with snap / Electrodes with pigtail
Model: Model A: Round Shape Electrode; Model B: Rectangular Shape Electrode; Model C: Palm shape Electrode; Model D: Elliptical Shape Electrode; Model E: Calabash Shape Electrode
Common Name: Cutaneous Electrode
Classification name: Cutaneous Electrode
Review Panel: Neurology
Models: Round Shape Electrode, Rectangular Shape Electrode, Palm Shape Electrode, Elliptical Shape Electrode, Calabash Shape Electrode
Product Code: GXY
Regulation Class: 2
Regulation Number: 882.1320

3. Predicate Device Information

510(K) Number: K160081
Company Name: CATHAY MANUFACTURING CORP.
Trade/Device Name: TENS Electrodes
Regulation Number: 882.1320
Regulatory Class: 2
Product Code: GXY

4. Device Description

The proposed Electrodes with snap / Electrodes with pigtail are non-sterile laminated, flexible structures composed of materials commonly used in this application: The electrodes are designed for single-patient application use. Because of the adhesive nature of the biocompatible hydro gel, no securing materials are required to secure the product to the patient's skin. The proposed product mainly consists of electrode pad and snap or pigtail. The electrode pad is available in Round Shape Electrode, Rectangular Shape Electrode, Palm shape Electrode, Elliptical Shape Electrode, and Calabash Shape Electrode.

5. Intended Use / Indications for Use

The proposed product 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 legally marketed electrical stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). It's for Over-the-Counter (OTC) use.

6. Test Summary

The proposed Electrodes with snap / Electrodes has been evaluated the safety and performance by lab bench testing as following:

- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- The electrode wire is compliance with 21 CFR 898 by construction review according to Sub-Clause 56.3 (c) in IEC 60601-1:1988 + A2:1995 (2nd edition)

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the proposed Electrodes with snap / Electrodes is substantially equivalent to the predicate devices quoted below. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject device**	**Primary Predicate**	**Remark**
Device Name	Electrodes with snap / Electrodes with pigtail	TENS Electrodes	--
510(K) Number	Applying	K160081	--
Product Code	GXY	GXY	SE
Intended Use / Indications for Use	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 legally marketed electrical stimulators, i.e.	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	SE

	TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). It's for Over-the-Counter (OTC) use.	(Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).It's for OTC use.	
Models of electrode pad	Mode A: Round Shape Electrode Model B: Rectangular Shape Electrode Model C:Palm Shape Electrode Model D:Elliptical Shape Electrode Model E: Calabash Shape Electrode	Model A: Round shape electrode Model B: Rectangular shape Electrode Model C: Crescent shape Electrode Model D: Square shape Electrode Model E:Calabash Shape Electrode	SE Note1
Surface area (Conductive surface)	Model A: 5 cm in diameter Model B: 5 x 11; 6 x 11 (cm^2) Model C: 7.6 x 4.8 (cm^2) Model D: 3 x 4.3 (cm^2) Model E: 8.4 x 4.8 (cm^2)	Model A: 5cm in diameter Model B: 5*10;6*10(cm^2） Model C: 2.4*4.2(cm^2) Model D: 3.2*3.2(cm^2) Model E: 8.0*5.5（cm^2）	SE Note1
OTC or prescription	For OTC Use	For OTC Use	SE
Design features	Substrate/Wire/Hydro-Gel Scrim/Conductive Fiber Carbon Conductive Film /liner	Substrate/Wire/Hydro-Gel Scrim/Conductive Fiber Carbon Conductive Film /liner	SE
Materials: ;	Non-woven fabric+ adhesive	Non-woven fabric+ adhesive	SE Note1
Substrate; Wire;;	Wire & Terminal coated PVC	Wire & Terminal coated PVC	
Hydro-gel;;	Hydro-gel	Hydro-gel	
Scrim;	nylon	PET fabric	
Conductive fiber;	Silver filaments	Carbon fiber + reinforcing fiber	
Carbon conductive Film;	Carbon Black	Poly-isobutylene, Carbon Black	
Biocompatibility	Complied with ISO 10993	Conforms to ISO10993	SE
Labeling	Confirm to 21 CFR Part 801	Confirm to 21 CFR Part 801	SE
Electrical	Individual pad impedance	Individual pad impedance	SE Note2

impedance	below 3000 ohms @ 10 Hz	below 200 ohms @ 60 kHz	
Adhesive performance on T_0	>= No. 14 steel ball (Diameter: 11.112 mm) following AS07-003 / GB/T4852-200	>= No. 14 steel ball (Diameter: 11.112 mm) following AS07-003 / GB/T4852-2002	SE
Adhesive holding strength performance	A sample pad with 40mm length and 40 mm width; Hang a weight of 500g without detach within 1min	A sample pad with 25mm length and 25 mm width; Hang a weight of 200g without detach within 30s	SE Note 2
Tensile Strength	Electrode is held up with a weight of 500g hung on the wire, and can hold on at least 1 minutes	Electrode is held up with a weight of 500g hung on the wire, and can hold on at least 1 minutes	SE
Conformability	No more than 10% of the adhesive area of the device shall have separated from the skin surface at 1 h after application	No more than 10% of the adhesive area of the device shall have separated from the skin surface at 1 h after application	SE
Impedance Distribution uniformity test	1) No significant deviation between resistance values measured for each combination mode. 2) The maximum value and the minimum value should be within ±10% of average value	1) No significant deviation between resistance values measured for each combination mode. 2) The maximum value and the minimum value should be within ±10% of average value	SE
Sterility	Non-sterile	Non-sterile	SE
Stability and shelf life	2 years	2 years	SE
Re-usable	For single patient	For single patient	SE
Intended population	Adult only	No specified population	SE Note 1

Comparison in Detail(s):

Note 1:
Although the “Model”, “ Surface area (Conductive surface)”, “Materials” and “ Intended population” of the subject device are different from the predicate devices, they are all complying with ISO 10993 requirements. So the differences of the function specifications will not raise any safety or effectiveness issue.

Note 2:

Although the “Electrical Impedance” and “Adhesive holding strength performance” are not totally same, they all of the subject devices are different from the predicate devices, they are all complying with performance testing. So the differences of the function specifications will not raise any safety or effectiveness issue.

Note 3:
“ SE” means substantially equivalent.

Conclusion

The subject device Electrodes with snap / Electrodes with pigtail has all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate devices.

8. Date of the summary prepared: January 5, 2018