January 5, 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: K171721
Trade/Device Name: Electrodes with silver conductive
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 15, 2017
Received: October 30, 2017

Dear Ms. 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)*
K171721

Device Name
Electrodes with silver conductive

Indications for Use *(Describe)*
Electrodes with silver conductive as Glove style, Socks style, Wristbands Style, Wrist sleeve, Elbow Pads Style and Knee Pads Style, Elbow Sleeve, are intended for use with legally marketed TENS stimulating device. The electrodes with silver conductive will deliver stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts can include such as hands (gloves), feet (socks), wrist, elbow and knee.

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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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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Fax: +86-755-86704558
Contact Person: Tony (Manager)
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Application Correspondent:
Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name: Electrodes with silver conductive
Common Name: Cutaneous Electrode
Review Panel: Neurology
Model: KM-406: Glove Style; KM-407: Socks Style; KM-408: Wristbands Style; KM-409: Elbow pads Style;
Product Code: GXY
Regulation Class: II
Regulation Number: 882.1320

3. Predicate Device Information

Sponsor	Neurotron Medical, Inc
Device Name	Theraknit Garments
510(k) Number	K053214
Product Code	GXY
Regulation Number	882.1320
Regulation Class	II

4. Device Description

Electrodes with silver conductive are conductive garments knitted from a continuous silver coated Nylon yarn into the form of gloves, socks, wrist sleeve, elbow Sleeve and knee sleeve. The conductivity is derived from the silver content of the Nylon yarn. The electrodes are available in free size. The elongation property of the nylon yarn provides some elasticity which ensures firm skin contact. The electrodes can be used dry or wet when in contact with the skin. The entire surface of each electrode is very conductive having a resistance of less than 2ohms per inch. This low resistance provides low current density with uniform current distribution.

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5. Intended Use / Indications for Use

Electrodes with silver conductive as Glove style, Socks style, Wristbands Style, Elbow Pads Style and Knee Pads Style, are intended for use with legally marketed TENS stimulating device. The electrodes with silver conductive will deliver stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts can include such as hands (gloves), feet (socks), wrist, elbow and knee.

6. Test Summary

Electrodes with snap / Electrodes with pigtail 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

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Electrode 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**	**Remark**
Device Name and Model	Electrodes with silver conductive Model: KM-406: Glove Style KM-407: Socks Style	Theraknit Garments	--

	KM-408: Wristbands Style KM-409: Elbow pads Style KM-410 : Knee Pads Style		
510(k) Number	Applying	K053214	--
Product Code	GXY	GXY	SE
Intended Use / Indications for Use	Electrodes with silver conductive as Glove style, Socks style, Wristbands Style, Wrist sleeve, Elbow Pads Style and Knee Pads Style, Elbow Sleeve, are intended for use with legally marketed TENS stimulating device. The electrodes with silver conductive will deliver stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts can include such as hands (gloves), feet (socks), wrist, elbow and knee.	The TheralKnit Garment electrodes are cutaneous to be used with legally marketed TENS stimulating device. The knitted garment electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts can include hand (glove), feet (socks), elbow or knee (sleeve), arm, leg, shoulder, back (pads).	SE
Design (Shape)	KM-406: Glove Style KM-407: Socks Style KM-408: Wristbands Style KM-409: Elbow pads Style KM-410: knee Pads Style	Electrode A: Glove Style Electrode B: Socks Style Electrode C: Sleeve Style Electrode D: Pads Style	SE Note1
Size	One size Below is size for when without stretched: KM-406: 200 (cm^2) KM-407: 285 (cm^2) KM-408: 95 (cm^2) KM-409: 160 (cm^2) KM-410: 236 (cm^2)	All sizes	SE Note 1
Conductive surface	One size Below is size for when without stretched: KM-406: 400 (cm^2) KM-407: 570 (cm^2) KM-408: 190 (cm^2) KM-409: 320 (cm^2) KM-410: 472 (cm^2)	All sizes	SE Note 1
Impedance Parameters	2 ohms resistance per inch	7 ohms resistance per inch	SE Notes 2
Patient Contacting Material	Silver plated nylon	Silver plated nylon	SE
Biocompatibility	Complied with ISO 10993-5, ISO 10993-10	Complied with ISO 10993-5, ISO 10993-10	SE

Washable or not	Washable	Washable	SE
Labeling	Confirm to 21 CFR Part 801	Confirm to 21 CFR Part 801	SE
Re-usable	For single patient	For single patient	SE

Comparison in Detail(s):

Note 1:

Although the “Shape”, “ Conductive surface” and “Size” of 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 “Impedance Parameters “are a little different from the predicate devices, The resistance of the knitted garment for both the subject device and the predicate devices are less than 7 ohms/inch which is very low relative to the delivery of the stimulation current. So they are both safe and effective.

Note 3:

“ SE” means substantially equivalent.

Conclusion

The subject device Electrodes with silver conductive 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