April 19, 2018

Guangzhou Xinbo Electronic Co., Ltd.
% Ms. Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, Guandong, 510006 Cn

Re: K172887
Trade/Device Name: XinBo Electrode (Model: Neck Therapy Pro - I, Neck Therapy Pro - II, Neck Therapy Pro - III, Neck Therapy Pro – IV)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 14, 2018
Received: January 19, 2018

Dear Ms. Cassie Lee:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172887

Device Name
XinBo Electrodes

Indications for Use *(Describe)*
XinBo Electrodes (Model: Neck Therapy Pro - I; Neck Therapy Pro – II; Neck Therapy Pro - III, Neck Therapy Pro - IV) are cutaneous electrodes to be used with legally marketed TENS stimulating devices for which stimulation of the back of the neck and upper back is appropriate. They will deliver the stimulation signals generated by the stimulator to the back of the neck, upper back and shoulder surface areas with which they are in contact.

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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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: Guangzhou Xinbo Electronic Co., Ltd.
Establishment Registration Number: K172887
Address: 2nd Building, Juntuo Industry Park, XingyeDadao, Nancun Town, Panyu District, Guangzhou City, Guangdong Province, China
Contact Person: Li Huifang (Manager)
Email: drtvsammy@hotmail.com

Application Correspondent:

Contact Person: Ms. Cecilia Ceng / 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: XinBo Electrodes
Common Name: Cutaneous Electrode
Review Panel: Neurology
Model: Neck Therapy Pro - I, Neck Therapy Pro - II, Neck Therapy Pro - III, Neck Therapy Pro - IV
Regulation Number: 882.1320

3. Predicate Device Information

Sponsor	Neurotron Medical, Inc	DRTV Asia Ltd.	AMPCAXE, LLC
Device Name	Theraknit Garments	Dr-Ho's Foot Pad Electrode	AMPCARE 50709 Series Electrodes
510(k) Number	K053214	K151693	K121483
Product Code	GXY	GXY	GXY
Regulation Number	882.1320	882.1320	882.1320
Regulation Class	II	II	II

4. Device Description

The electrodes can be use together with any legally marketed TENS stimulating devices for which stimulation of the back of the neck and upper back is appropriate. For the silver coated Nylon yarn electrodes, they can be used dry or wet when in contact with the skin. The entire surface of each

electrodes is very conductive having a resistance of less than 7 ohms per inch; For the model “Neck Therapy Pro - III”, conductive silicone rubber having a resistance of less than 7 ohms per inch, these low resistance provides low current density with uniform current distribution.

5. Intended Use / Indications for Use

XinBo Electrodes (Models: Neck Therapy Pro - I, Neck Therapy Pro - II, Neck Therapy Pro - III, Neck Therapy Pro - IV) are cutaneous electrodes to be used with legally marketed TENS stimulating devices for which stimulation of the back of the neck and upper back is appropriate. They will deliver the stimulation signals generated by the stimulator to the back of the neck, upper back and shoulder surface areas with which they are in contact.

6. Test Summary

XinBo Electrodes have 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 IEC 60601-1 (version 3.1, clause 8.5.2.3) evaluation.
- Performance test (hot spots verification test) according to manufacturer self-requirements.
- Usability study according to IEC 60601-1-6, IEC 62366, and “FDA Guidance for Applying Human Factors and Usability Engineering to Medical Devices”

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of subject device are substantially equivalent to the predicate devices.

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**	**Predicate Device 3**	**Remark**
Device Name and Model	XinBo Electrodes (Models: Neck Therapy Pro - I, Neck Therapy Pro - II, Neck Therapy Pro - III, Neck Therapy Pro - IV)	Theraknit Garments	Dr-Ho's Foot Pad Electrode	AMPCARE 50709 Series Electrodes	--
510(k) Number	K172887	K053214	K151693	K121483	--
Product Code	GXY	GXY	GXY	GXY	SE
OTC or Rx-only	OTC	Rx-only	OTC	Rx-only	SE
Intended Use / Indications for Use	XinBo Electrodes (Models: Neck Therapy Pro - I, Neck Therapy Pro - II, Neck Therapy Pro - III, Neck Therapy Pro - IV) are cutaneous electrodes	The TheraKnit Garment Electrodes are cutaneous electrodes to be used with legally marketed TENS stimulating device. The knitted	The Cutaneous Electrodes, "Dr-Ho's Foot Pad Electrodes", are intended to be used with legally marketed electrical stimulating devices	AMPCA RE 50709 Series of cutaneous electrodes are intended to be used to apply electrical stimulation current to the patient's skin.	SE

	to be used with legally marketed TENS stimulating devices for which stimulation of the back of the neck and upper back is appropriate. They will deliver the stimulation signals generated by the stimulator to the back of the neck, upper back and shoulder surface areas with which they are in contact.	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).	such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The cutaneous electrodes will deliver the stimulation signals generated by the stimulator to the bottom of the feet which they are in contact with.	Example electrical stimulation current applications of these electrodes are: a) Transcutaneous Electrical Nerve Stimulation (TENS) for pain relief b) Electrical muscle stimulation (EMS) for neck muscle stimulation. c) Functional electrical stimulation (FES) d) Galvanic stimulation e) Microcurrent electrical nerve stimulation (MENS) J) Interferential (IF) stimulation g) Neuromuscular electrical stimulation (NMES), including for muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.	
Body Parts to Use on	Back of the neck, upper back and shoulder	Hand, feet, elbow or knee, arm, leg, shoulder, back	Bottom of the feet	Back of the neck	SE
Design (Shape)	Model A: Neck Therapy Pro - I Model B: Neck Therapy Pro - II Model C: Neck Therapy Pro - III Model D: Neck Therapy Pro - IV	Electrode A: Glove Style Electrode B: Socks Style Electrode C: Sleeve Style Electrode D: Pads Style	Electrode A: foot-shaped Electrode	--	SE Note 1
Dimensions	Model A: For the whole product: 260 x 297.8 mm For only the electronic pads part: 4 electrodes on each models, two of them are: 65 mm in diameter, the other two of them are irregularly: 75 mm in diameter and about 105 mm long Model B: For the whole product:	--	--	--	SE Note 1

	208 x115 x110 mm For only the electronic pads part: 2 electrodes on each models, each electrode is: 50 mm in diameter Model C: For the whole product: 264.2 x 298.5 mm For each the electronic pads part: 6 electrodes on each models, each electrode is: 48 x26.2 mm^2 Model D: For the whole product: 300x 450 x 110mm For each electronic pads part: 4 electrodes on each models, each electrode is: 45 mm in diameter				
Impedance Parameters	For Model A: 7 ohms per inch For Model B: 7 ohms per inch For Model C: Less than 7 ohms per inch For Model D: 7 ohms resistance per inch	7 ohms resistance per inch	<7 ohms per inch	<7 ohms per inch	SE
Patient Contacting Material	For Model A: Silver plated nylon (Silver Fibre Knitted Fabric), cotton (Crystal Super Cashmere) For Electrode B: Silver plated nylon (Silver Fibre Knitted Fabric), cotton (Crystal Super Cashmere and Mutispandex) For Electrode C: Conductive silicone rubber, PU Foam For Electrode D: Silver plated nylon (Silver Fibre Knitted Fabric), cotton (Crystal Super Cashmere)	Silver plated nylon	Conductive silicone rubber	--	SE Note 1
Lead Wire Type and	Lead wire with female socket, or snap button	Lead wire with female socket, or snap button	Connector Lead wire 080” female socket	--	SE

Characteristics	with male snap connector	with male snap connector	connector		
Operating Environment	Temperature: 5~40°C Humidity: ≤ 80%RH Atmospheric Pressure: 86~106kPa	Temperature: 5~40°C Humidity: ≤ 80%RH Atmospheric Pressure: 86~106kPa	Temperature: 5~40°C Humidity: ≤ 80%RH Atmospheric Pressure: 86~106kPa	--	SE
Storage Environment	Temperature: -20 ~ 55°C Humidity: ≤ 95% RH Atmospheric Pressure: 50~106 kPa	Temperature: -20 ~ 55°C Humidity: ≤ 95% RH Atmospheric Pressure: 50~106 kPa	Temperature: -20 ~ 55°C Humidity: ≤ 95% RH Atmospheric Pressure: 50~106 kPa	--	SE
Biocompatibility	Complied with ISO 10993-5, ISO 10993-10	Complied with ISO 10993-5, ISO 10993-10	Complied with ISO 10993-5, ISO 10993-10	Complied with ISO 10993-5, ISO 10993-10	SE

Comparison in Detail(s):

Note 1:

Although the “Design (shape)”, “Dimensions”, and “Patient Contacting Material” are a little different from the predicate devices, they all comply with ISO 10993 requirements. So the differences will not raise any safety or effectiveness issue.

Final Conclusion:

The subject device XinBo Electrodes (Models: Neck Therapy Pro - I, Neck Therapy Pro - II, Neck Therapy Pro -III, Neck Therapy Pro -IV) are Substantial Equivalent to the predicate devices.

8. Date of the summary prepared: April 20, 2018