June 1, 2021

Well-Life Healthcare Limited
Jenny Hsieh
Official Correspondent
6F., No, 168, Lide St., Jhonghe District
New Taipei City, 235
Taiwan

Re: K200942
Trade/Device Name: Well-Life Garment Electrodes (GM Series)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: April 23, 2021
Received: April 30, 2021

Dear Ms. Hsieh:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200942

Device Name
Well-Life Garment Electrodes (GM Series)

Indications for Use *(Describe)*
The Well Life Garment Electrodes (GM Series) are intended to be used with legally marketed TENS devices.

The Well-Life Garment Electrodes (GM Series) will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact.

They can be used on body parts such as arm and elbow.

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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510(K) Summary

1. Type of Submission: Traditional 510(k)

2. Preparation date: 13th May, 2021

3. Submitter: Well-Life Healthcare Ltd.

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New Taipei City, 23512, Taiwan
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Contact: Jenny Hsieh
(jenny@welllifehealthcare.com.tw)
Registration number: 3006850006

4. Identification of the device:

Device Name: Well-Life Garment Electrodes (GM Series)
Common or usual name: Garment Electrode
Classification name: Electrode, Cutaneous
Device Models:
(RX)
Well-Life Garment Electrode – Arm (GM-AM-R-X00)
Well-Life Garment Electrode – Elbow (GM-EB-R-X00)
(OTC)
Well-Life Garment Electrode – Arm (GM-AM-O-X00)
Well-Life Garment Electrode – Elbow (GM-EB-O-X00)

Classification Panel: Neuromodulation and Physical Medicine Devices
Device Classification: II
Regulation Number: 882.1320
Panel: Neurology
Product Code: GXY

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5. Identification of the Predicate Device:

Predicate Device Name:	Theraknit Garment
Manufacture:	Neurotron Medical, Inc
Regulation Number:	882.1320
Product Code:	GXY
510(k) Number:	K053214

Predicate Device Name:	Electrodes with Silver Conductive
Manufacture:	Shenzhen Konmed Technology Co.
Regulation Number:	882.1320
Product Code:	GXY
510(k) Number:	K171721

6. Intended Use and Indications for use of the Subject Device:

The Well Life Garment Electrodes (GM Series) are intended to be used with legally marketed TENS devices.

The Well-Life Garment Electrodes (GM Series) will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact.

They can be used on body parts such as arm and elbow.

7. Description of the Device:

Well-Life Garment Electrodes (GM, Series), Models AM and EB, are intended to be used with legally Marketed Transcutaneous Electrical Nerve Stimulation (TENS) devices which could be used in place of traditional cutaneous electrode patches. The Well-Life Garment Electrodes (GM Series) are blended with Non-conductive textiles (polyurethane, nylon and polyester) and conductive textiles (Silver Fabric). Non-conductive area is used to fix and support Well-Life Garment Electrodes (GM Series) on the body. Two types of Garment Electrodes are designed.

The different series of model means different placement of the garment electrode. For “AM” it is to be place around the arm with conductive areas are on the upper arm and lower arm and there are two sets of snap facing outward, finally for “EB” it is to be place around the elbow with conductive area surrounds the elbow and

there are one sets of snap facing outward. There are three sizes for each series of model (S/M/L). The conductive area between different sizes is fixed. There is four conductive area divided into upper arm area and lower arm area on model “AM”, the areas is a pair of 39 cm^2 and a pair of 39 cm^2. There is only two conductive area on model “EB”, the areas is a pair of 25.5 cm^2.

By adjusting the area of the non-conductive area, the customer's body curve can be fitted. Conductive area is used as a transmission interface which enabling electrical stimulation devices to transmit signals to the skin. The devices must be used wet when in contact with the skin. When using Well-Life Garment Electrodes (GM Series), buckle the one port of lead wire or any connection terminal from legally marketed stimulator to the set of closest snap buttons on Garment Electrodes. Make sure electrical signals could reach the path from electrical stimulation to the Garment Electrodes.

For Garment Electrodes with multiple sets of buttons, only one set of buttons can be used at a time. The surface of conductive area has a resistance of less than 14 ohms per inch. The signal is generated by an electrical stimulator, and is transmitted evenly through the wire to the conductive area of the Garment Electrodes, and transmitted to the skin.

8. Statement of conformity

List of FDA-recognized voluntary consensus standards cited in this submission.

Recognition Number	Standard Designation Number And Date	Title Of Standard	Date Of Recognition
2-258	ISO 10993-1 Fifth Edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	01/14/2019
2-245	ISO 10993-5 Third Edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	02/23/2016
2-174	ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	07/26/2016
2-191	ISO 10993-12 Fourth Edition 2012-07-01	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	07/26/2016
17-16	IEC 60601-2-10 Edition 2.1 2016-04	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	06/27/2016
5-125	ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices	12/23/2019

9.Non-Clinical Testing Summary:

Non-clinical testing was conducted to verify that the subject devices met all design specifications, demonstrated safety based on current industry standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed:

1) Biocompatibility Patient contacting components are in compliance with ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, including cytotoxicity (ISO 10993-5 Third Edition 2009-06-01), sensitization (ISO 10993-10 Third Edition 2010-08-01), irritation (ISO 10993-10 Third Edition 2010-08-01) and Sample preparation and reference materials (ISO 10993-12 Fourth Edition 2012-07-01)
2) Performance Bench testing was performed to verify the performance to specifications of the proposed device and included the following:
   - Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (IEC 60601-2-10 Edition 2.1 2016-04)
   - Impedance Distribution Uniformity Testing is for verifying the conductive properties of subject device. Uniform and safety shall be within the specification, so that there aren't any "hot spots" that may result in user discomfort or burns.
   - Shelf Life (Accelerated Aging) Testing (ASTM F1980:2016)
   - Reusability of the maximum duration, of the maximum number of times and of the maximum number of re-wash (In-house specification)

10. Substantial Equivalence Determination:

10.1 Substantial Equivalence Comparison to Predicate Device

Elements of Comparison	Subject Device	Primary Predicate	Secondary Predicate	Remark
Company	Well-Life Healthcare Ltd	Neurotron Medical , Inc.	Shenzhen Konmed Technology Co	--
Device Name	Well-Life Garment Electrodes (GM series)	TheraKnit Garment Electrode	Electrodes with silver conductive	--
Regulation Number	882.132	882.132	882.132	Same
Product K Number	Applying	K053214	K171721	--
Product code	GXY	GXY	GXY	Same
OTC/Rx	OTC/Rx	Rx	OTC	Similar

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Intended Use/ **Indication for use**	The Well Life Garment Electrodes (GM Series) are intended to be used with legally marketed TENS devices. The Well-Life Garment Electrodes (GM Series) will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. They can be used on body parts such as arm and elbow.	The TheraKnit Garment electrodes are cutaneous to be used with legally 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 included hand(glove), feet (socks), elbow or knee (sleeve),arm, leg, shoulder, back(pads)	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.	Similar (Note.1)

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Design (Shape)/ Model	GM-AM-R-X00 / GM-AM-O-X00 Arm RX/OTC GM-EB-R-X00 / GM-EB-O-X00 Elbow RX/OTC	Electrode A: Glove Style Electrode B: Socks Style Electrode C: Sleeve Style Electrode D: Pads Style	KM-406: Glove Style KM-407: Socks Style KM-408: Wristbands Style KM-409: Elbow pads Style KM-410:Knee Pads Style	Similar (Note.2)
Size	Arm (S/M/L) Elbow (S/M/L)	All sizes	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)	Similar (Note.2)

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Anatomical locations of use	Arm Elbow	Hands Feet Elbow Knee Arm Leg Shoulder Back	Hands Feet Wrist Elbow Knee	Similar (Note.2)
Impedance Parameters	14 ohms resistance per inch	7 ohms resistance per inch	2 ohms resistance per inch	Similar (Note.2)
Biocompatibility	Complying with ISO 10993 requirements	Complying with ISO 10993 requirements	Complying with ISO 10993 requirements	Same (Note.2)
Power Source	legally Marketed Electrical Stimulator	legally Marketed Electrical Stimulator	legally Marketed Electrical Stimulator	Same
Maximum Average Current Density (@500 Ω)	0.254 mA/cm^2 (arm) 0.392 mA/cm^2 (elbow)	not publicly available	not publicly available	
Maximum Peak Power Density (@500 Ω)	1.255 mW/cm^2 (arm) 1.958 mW/cm^2 (elbow)	not publicly available	not publicly available	

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Washable or not	Washable	Washable	Washable	Similar (Note.3)
Re-usable	For single Patient	For single Patient	For single Patient	Same
Conductive surface area	Arm: Area 1: 39.00 cm^2 Area 2: 39.00 cm^2 Elbow: Area 1: 25.50 cm^2	Not publicly available	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)	
Patient contacting material	Non-conductive textiles (polyurethane, nylon and polyester) and conductive textiles (Silver Fabric)	Silver plated nylon	Silver plated nylon	

Comparison in Detail(s):

Note 1: The description are partially different among Subject Device, Primary Predicate Devices, and secondary Predicate Devices but the Intended Use/ Indication for use are similar. They are all used to deliver the stimulation signals generated by electrical stimulator to the body surface.

Note 2: Electrode conductive area and Impedance Parameters
Although the subject device has 14 ohms per inch, which is different from the predicate device, “Maximum Average Current Density” and “Maximum Peak Power Density” property are similar and do not raise new questions of safety or effectiveness.
The standard of "Maximum Average Current Density" refers to “IEC60601-2-10 Clause 201.4.2” and the standard of “Maximum Peak Power Density” refer to “Guidance Document for Powered Muscle Stimulator 510K Section 3.” Indicating similar performance and safety between subject device and predicate device. Otherwise the subject devices are complying with ISO 10993 requirements. So the differences of the function specifications will not raise any safety or effectiveness issue. For detailed measurement data, please refer to the above table. The subject device are Substantially Equivalent to the predicate device.

Note 3: Washable or not.

Subject Device, Primary Predicate K053214 and Secondary Predicate K171721 are made of textiles and can be washed. The subject device are Substantially Equivalent to the predicate device.

10.2. Conclusion:

Although the Note 1: description of Intended Use, Note 2: Design (shape) and size, Note 3: Electrode conductive area and Impedance Parameters, Note 4: Washable or not aren't exactly as same as the Predicate devices, all of their functions and performance are applying in the corresponding device, such as Electrical Stimulator, are substantially equivalent with Predicate device. After Comparison and Evaluation, the subject device Well-Life Garment Electrodes (GM series) has similar features to predicate devices. The few differences are explained and do not impact of the safety and effectiveness. Thus, the subject device is substantially equivalent with Predicate device.