June 1, 2018

Media Plus, LLC
% Sharon Blinkoff
Counsel
Locke Lord LLP
200 Vesey Street
New York, New York 10281

Re: K171798
Trade/Device Name: Silverwear Silver Pro Garment Device
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: March 1, 2018
Received: March 5, 2018

Dear Sharon Blinkoff:

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 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)*
K171798

Device Name
Silverwear Silver Pro
Garment Device

Indications for Use *(Describe)*
The Silverwear SilverPro Series Conductive Garments are cutaneous electrodes to be used with legally marketed TENS or NMES devices. The knitted garment electrodes are non-sterile reusable OTC conductive garments that are intended to 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), wrist (sleeve), elbow or arm (sleeve), knee or leg (sleeve), knee high stockings, ankle (sleeve), back band, and shoulder band.

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

Applicant: Media Plus LLC
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Contact: Rita Vaccaro

Phone number: 201-541-1222 ext. 300

Distributor: SilverWear USA, LLC
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Englewood Cliffs, NJ 07632
(844-884-4499)

Contact: Rita Vaccaro
201-541-1222 ext. 300

Contact

For 510k

Submission : Sharon Blinkoff
Locke Lord LLP
200 Vesey Street
New York NY 10281
Sharon.blinkoff@lockelord.com
(232-912-2983)

Date of Submission:

Proprietary Name: Silverwear SilverPro Garment Electrodes
Common Name: Cutaneous Electrodes 21 CFR 882.1320
Product Code: GXY Cutaneous Electrodes
Panel: Neurological Devices

Trade Name: Silverwear SilverPro model numbers:
SP 1001, SP 1002, SP 1002, SP 1003, SP 1004, SP 1005,
SP 1006, SP 1007, SP 1008, SP 1009

A. Legally Marketed Predicate devices

1. Theraknit Garment Electrodes k053214
2. Cutaneous Electrodes k141076 – secondary predicate

B. Device Description

The Silverwear SilverPro garment electrodes are conductive garments that are made from material which is knitted from primarily nylon yarn with minor amounts of lycra, spandex to achieve a stretch fabric for a snug garment fit polyester for tactile qualities and polyester sheathed carbon yarn and pure silver coated nylon fibers to provide conductivity. The knitting follows standard knitting procedures with the conductive knitted material being fabricated into wearable electrode garments which are provided in multiple sizes of various garment configurations including; gloves, bands, socks, and sleeves. The stretch characteristics of the material provide sufficient elasticity to ensure firm surface contact with the skin. The design of the devices is such that they can be used skin by reversing the surface contacting the skin. The entire surface of the garment electrode is very conductive having a resistance of less than 5 ohms per inch. This provides low current density with uniform current distribution to enable efficient use of these garment electrodes for use in TENS (transcutaneous electrical nerve stimulators) and NMES (powered muscle stimulator devices). The Silverwear SilverPro garment electrodes are non- sterile external devices which are designed for single patient, for multiple uses and are intended for OTC use with FDA Cleared TENS and NMES class II devices.

C. Intended Use

The Silverwear SilverPro garment cutaneous electrodes are provided in various sizes of several forms of garments such as gloves, socks, sleeves knee pads, pads and bands are intended for use with legally marketed electrostimulation TENS and NMES devices, to deliver uniformly to the skin low level stimulation current for pain relief. The garment electrodes can be used on external body parts of the body with external application to hands, feet, arms legs, low back, knee and shoulder for pain relief using electrostimulation. The devices are intended for OTC use, for external application to intact skin of low dose current density with uniform distribution which follows the conductive materials knitted into the fabric.

D. Comparison to Predicate Device

Elements of comparison	**Subject Device**	**Primary Predicate**	**Secondary Predicate**	
Company	Silverwear SilverPro Garment	Neurotron Medical, Inc.	Shenzhen Konmed Technology Co., Ltd	--

Device Name	Silverwear SilverPro wearable therapy garments	TheralKnit garment	Electrodes with silver conductive Model: KM-406: Glove Style KM-407: Socks Style KM-408: Wristbands Style KM-409: Elbow pads Style KM-410 : Knee Pads Style	--
Regulation Number	882.1320	882.1320	882.1320	same
Product k number	Applying	K053214	K171721	--
code	GXY	GXY	GXY	same
OTC / Rx	OTC	Rx	OTC	similar
Intended Use / Indications for Use	The Silverwear SilverPro Series Conductive Garments are cutaneous electrodes to be used with legally marketed TENS or NMES devices. The knitted garment electrodes are non-sterile reusable OTC conductive garments that are intended to 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), wrist (sleeve), elbow or arm (sleeve), knee or leg (sleeve), knee high stockings, ankle (sleeve), back band, and shoulder band.	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).	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.	same
Design (Shape)	Electrode A: Glove Style Electrode B: Wrist Sleeve Electrode C: Elbow/Arm Sleeve Electrode D: Knee/Leg Sleeve Electrode E: Knee High Socks Electrode F: Ankle Sleeve Electrode G: Back Band Electrode H: Shoulder Band	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
Size	All Sizes	All Sizes	One size Below is size for when without stretched: KM-406: 200 (cm2) KM-407: 285 (cm2) KM-408: 95 (cm2) KM-409: 160 (cm2) KM-410: 236 (cm2)	
Impedance Parameters	7 ohms resistance per inch	7 ohms resistance per inch	2 ohms resistance per inch	similar

Washable or not	Washable	Washable	Washable	same
Re-usable	For Single Patient	For Single Patient	For Single Patient	same
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	same
Patient Contacting Material	Silver plated nylon	Silver plated nylon	Silver plated nylon	same

E. Substantial Equivalence Summary

The Silverwear SilverPro device garment cutaneous electrodes are medical devices that have the same design features, construction, indication, intended use, conductivity, electrical connection and target population as the legally marketed predicate devices. The Silverwear SilverPro devices have the same technological characteristics as the predicate devices. Both the Silverwear SilverPro and the predicate devices receive electrostimulation signals from legally marketed TENS or NMES devices through a standard electrical connection of an adhesive electrode which adhesively connects to the Silverwear SilverPro device and is wired to the TENS or NMES device. Both the Silverwear SilverPro and the predicate devices are washable and intended for multiple uses by a single patient with intact skin.

F. Technological Characteristics

The Silverwear SilverPro garment electrodes are made from silver plated nylon yarn and a polyester sheath yarn with carbon filling, using a conventional knitting process. The fabric is highly conductive and provides less than 5 ohms resistance per inch. The actual devices which are fabricated into multiple different garment forms with each form being designed to accept an adhesively applied electrode component from the NMES or TENS device which is the source of the current that is delivered by the garment electrodes to the target skin tissue. The Silverwear SilverPro devices are non- sterile multiple use devices which are washable using conventional detergents. Bench tests of the fabric show that the garment electrodes do not change their inherent conductivity with multiple washings so that there is no significant adverse effect on the conductivity of the device or its inherent ability to deliver low dose current density uniformly to the skin of the wearer even after multiple washings. The Silverwear SilverPro garment electrode provide a snug elastic fit against the skin based upon the low mild elastic properties of the yarn used to fabricate the devices, these elastic properties insure proper a snug fit for delivery of the current generated by the TENS or NMES devices.

G. Software

There is no software used in the Silverwear SilverPro devices

H. Testing

Bench testing has been conducted on the fabric used to fabricate the various forms of the Silverwear SilverPro devices to demonstrate that that the fabric and the devices meet design controls in terms of conductivity and resistivity, and uniform delivery of low doses of current all

consistent with that of the predicate devices. Resistivity testing was conducted using standard industry testing to confirm that the resistivity met the standards of less than 7 ohms per inch through multiple washings to confirm the multiple use aspects of the device.

Biocompatibility tests were conducted on the Silverwear SilverPro devices, which are intended for external use only, on intact skin of limited body areas for less than 24 hour. Biocompatibility was conducted using tests methods to determine Cytotoxicity, Sensitization and Irritation of Cutaneous Reactivity.

I. The subject device:
   a. is OTC only
   b. Intended for limited external exposure only not for internal use
   c. Is for application to intact skin and not for application on mucosal areas
   d. Is for application to limited areas of skin and for limited duration of use under 24 hours and as prescribed in the TENS and NMES devices for which use of these wearable electrodes are intended. These devices are not intended for use in mucosal areas

J. Conclusions

The subject Silverwear SilverPro devices are comparable in design specifications to the predicate garment devices and like the predicate garment devices come in multiple versions all of which have the same intended use, are intended to be used on the same patient population, with the same technical electrical performance to deliver low doses of current to provide electrical stimulation to the skin, which like the predicate devices are intended to be used with the same FDA cleared OTC TENS or NMES predicate devices as the predicate devices. Testing has demonstrated that this Silverwear SilverPro device is in terms of conductivity and resistivity relies on the same principles of Technology as the comparable predicate devices and in terms of design, material of fabrication, method of application, and intended use and performance is comparable to its predicate devices in delivering the uniform delivery of low dose current generated by FDA cleared OTC TENS or NMES devices. The proposed device presents no new technological, safety or effectiveness differences from those of the predicate class II garment electrode devices. Thus, the Silverwear SilverPro garment electrodes are substantially equivalent to the predicate devices.