July 8, 2021

BioWave Corporation
% Dave McGurl
Director, Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20005

Re: K203158
Trade/Device Name: BioWave BioWraps
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 22, 2020
Received: October 22, 2020

Dear Dave McGurl:

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, Sub part 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)*
K203158

Device Name
BioWave BioWraps

Indications for Use *(Describe)*
The BioWave BioWraps are cutaneous electrodes to be used with legally marketed BioWave branded neurostimulators. The knitted garment electrodes are non-sterile reusable prescription-use and 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 include hand/wrist, elbow, foot/ankle, knee, and lower back.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name: BioWave BioWraps

Manufacturer:
BioWave Corporation
8 Knight Street, Suite 201
Norwalk, CT 06851

Contact:
Bradford Siff
Founder & President
BioWave Corporation
8 Knight Street, Suite 201
Norwalk, CT 06851
Phone: 203-247-9020 or 203-635-7175
Fax: 203-286-2518
brad.siff@biowave.com

Prepared by:
Dave McGurl
Director, Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
Office: 202.552.5797
Fax: 202.552.5798
dmcgurl@mcra.com

Date Prepared: December 14, 2020

Classifications: 21 CFR §882.1320, Cutaneous Electrodes

Class: II

Product Codes: GXY

Indications for Use:
The BioWave BioWraps are cutaneous electrodes to be used with legally marketed BioWave branded neurostimulators. The knitted garment electrodes are non-sterile reusable prescription-use and 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 include hand/wrist, elbow, foot/ankle, knee, and lower back.

Device Description:
The BioWave BioWraps are washable, wrappable bands made from a stretchable neoprene-like outer and silver fiber conductive inner fabric. The electrodes are secured to the skin through the wrapping of the bands. The BioWraps are intended for use on the hand/wrist, elbow, foot/ankle,

knee, and lower back. When used alongside a conductive cream, the electrodes provide a low current density with uniform current distribution. The BioWraps are to be used alongside cleared BioWave neurostimulator devices (the BioWavePRO® RX (K052289), BioWaveHOME® RX (K152437), and BioWaveGO® OTC (K180943)).

Predicate Devices:
The BioWave Corporation's BioWave BioWraps are substantially equivalent to the primary predicate previously cleared with respect to indications, design, function, and materials, as outlined below.

Manufacturer	Device Name	K-Number
Primary Predicate		
SilverWear USA, LLC.	SilverPro Garment Electrodes	K171798
Reference Predicate		
Shenzhen Konmed Technology, Co. LTD.	Electrodes with Silver Conductive	K171721
Prizm Medical, Inc.	Electro-Mesh Sock, Wrap, and Sleeve Electrodes	K944487

Performance Testing Summary:
Bench testing conducted on the BioWave BioWraps has demonstrated that the garments meet design controls with regard to conductivity, resistivity, impedance, and uniform delivery of low doses of current consistent with that of the cited predicate. Reusability has been duly demonstrated. Biocompatibility testing, inclusive of cytotoxicity, sensitization, and irritation and cutaneous reactivity, conducted on the BioWave BioWraps met the established acceptance criteria per ISO 10993-5 and 10993-10.

Substantial Equivalence:

Element of Comparison	Subject Device	Primary Predicate	Reference Predicate	Reference Predicate	Differences
Company	BioWave Corporation	SilverWear USA, LLC.	Shenzhen Konmed Technology, Co. LTD.	Prizm Medical, Inc.	--
Device Name	BioWave BioWraps	SilverPro	Electrodes with Silver Conductive	Electro-Mesh Sock, Wrap, and Sleeve Electrodes	--
Regulation Number	882.1320	882.1320	882.1320	882.1320	*Same*
Clearance Number	--	K171798	K171721	K944487	*Same*
Product Code	GXY	GXY	GXY	GXY	*Same*
OTC / Rx	OTC and Rx	OTC	OTC	OTC	*Similar*
Intended Use / Indications for Use	The BioWave BioWraps are cutaneous electrodes to be used with legally marketed BioWave branded neurostimulators. The knitted garment electrodes are non-sterile reusable prescription-use and OTC conductive garments that are intended	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	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	*Not Available*	*Similar, except K944487*

Element of Comparison	Subject Device	Primary Predicate	Reference Predicate	Reference Predicate	Differences
	to deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts include hands/wrist, elbow, foot/ankle, knee, and lower back.	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.	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.		
Design (Shape)	Wrappable bands for the hand/wrist, elbow, foot/ankle, knee, and lower back	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	KM-406: Glove Style KM-407: Socks Style KM-408: Wristbands Style KM-409: Elbow pads Style KM-410: knee Pads Style	Knitted series of garments inclusive of socks, gloves, sleeves, and back braces.	*Similar*
Size	All BioWraps are available in small/medium (S/M) and large/extra-large (L/XL) sizes: <u>Low Back</u>: - *S/M:* 28-38" Waist - *L/XL:* 38-50" Waist <u>Knee</u>: - *S/M:* 12-15.5" circumference around the kneecap - *L/XL:* 15.5 - 19" circumference around the kneecap <u>Foot/Ankle</u>: - *S/M:* Women's shoe size 6-9, Men's shoe size 7-8.5 - *L/XL:* Women's shoe size 9.5-11, Men's shoe size 9-13 <u>Elbow</u>: - *S/M:* 8-12" circumference around the elbow joint with arm extended - *L/XL:* 12-16" circumference around the elbow joint with arm extended <u>Hand/Wrist</u>:	Information not publicly available	Gloves KM-406: 200 cm^2 Socks KM-407: 285 cm^2 Wristbands KM-408: 95 cm^2 Elbow pads KM-409: 160 cm^2 Knee Pads KM-410: 236 cm^2	Information not publicly available	*Similar*

Element of Comparison	Subject Device	Primary Predicate	Reference Predicate	Reference Predicate	Differences
	- *S/M:* 6-9" circumference around the dominant hand - *L/XL:* 9-12" circumference around the dominant hand				
Impedance Parameters	1.27 ohms resistance per inch	7 ohms resistance/inch	2 ohms resistance/inch	Information not publicly available	*Similar*
Washable / Not Washable	Washable	Washable	Washable	*Not Available*	*Same except K944487*
Reusable	Single Patient, Reusable	Single Patient, Reusable	Single Patient, Reusable	Single Patient, Reusable	*Same*
Biocompatibility	Compliant with ISO 10993-5 and -10	Compliant with ISO 10993-5 and -10	Compliant with ISO 10993-5 and -10	*Not Available*	*Same, except K944487*
Patient Contacting Materials	Silver Fiber	Silver-coated Nylon	Silver-coated Nylon	Information not publicly available	*Similar*

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

The subject electrodes are made from silver fiber and is highly conductive and provides less than 1.27 ohms resistance per inch which is similar or less than the predicate devices. The actual devices which are fabricated into multiple different garment forms and is connected to a TENS device which is the source of the current that is delivered by the garment electrodes to the target skin tissue. The subject 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 treatment uniformly to the skin of the wearer even after multiple washings. The biocompatibility testing demonstrates the material is acceptable in comparison to the predicates for the intended use.

The subject devices, the BioWave BioWraps, were demonstrated to be substantially equivalent to the predicate and reference devices cited in the table above with respect to indications, design, materials, function, availability (i.e., over-the-counter use), and/or performance.

Conclusion:
The BioWave BioWraps have been found to be substantially equivalent to the previously cleared predicate device, SilverPro Garment Electrodes (K171798), and the included reference predicates, Electrodes with Silver Conductive (K171721) and Electro-Mesh (K944487), with respect to indications, design, materials, function, availability, and performance.