June 3, 2026

Biowave Corporation
% Emily Andre
Associate Director, Neurology Regulatory Affairs
MCRA, an IQVIA Business
803 7th St. NW
4th Floor
Washington, District of Columbia 20001

Re: K261522
Trade/Device Name: BioWave BioWraps
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: May 7, 2026
Received: May 7, 2026

Dear Emily Andre:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261552

Please provide the device trade name(s).

BioWave BioWraps

Please provide your Indications for Use below.

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 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/wrist, elbow, foot/ankle, knee, thigh/calf, cervical neck and lower back.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary - K261522

Device Trade Name: BioWave BioWraps

Manufacturer:
BioWave Corporation
19 Newtown Turnpike
Westport, CT 06880

Contact:
Bradford Siff
Founder & President
BioWave Corporation
19 Newtown Turnpike
Westport, CT 06880
Phone: 203-247-9020
Fax: (475) 444-3400
brad.siff@biowave.com

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 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 hand/wrist, elbow, foot/ankle, knee, thigh/calf, cervical neck 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, thigh/calf, cervical neck 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 current submission adds 2 new BioWraps for the thigh/calf and cervical neck. The addition of these two new BioWraps necessitates an update to the indications for use which explicitly describe the anatomical locations of the cleared BioWraps. These anatomical locations are currently treated by traditional electrodes used with the BioWave family of devices and do no introduce new questions of safety and effectiveness. The generation of a wrappable electrode only provides more options for patients to engage in use of the BioWave family of devices. The BioWave BioWraps are available as

prescription use only with BioWavePRO® RX and BioWaveHOME® RX neurostimulators.

Predicate Device:
The BioWave Corporation's BioWave BioWraps are substantially equivalent to the primary predicate (BioWave BioWraps - K203158) previously cleared with respect to indications, design, function, and materials, as outlined below.

Performance Testing Summary:
Bench testing conducted on the BioWave BioWraps has previously 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 and biocompatibility have also been previously demonstrated.

Substantial Equivalence:

Element of Comparison	**Primary Predicate** K203158 BioWave BioWraps	**Subject Device** K261522 BioWave BioWraps	**Comparison**
Manufacturer	BioWave Corporation	BioWave Corporation	Same
Device Name	BioWave BioWraps	BioWave BioWraps	Same
Regulation Number	882.1320	882.1320	Same
Product Code	GXY	GXY	Same
OTC / Rx	OTC and Rx	Rx	Similar. The BioWave BioWraps are no longer used with the BioWaveGo device which is available OTC.
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 to deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts include hand hands/wrist, elbow, foot/ankle, knee, and lower back.	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 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 hands/wrist, elbow, foot/ankle, knee, thigh/calf, cervical neck and lower back.	Similar. The current submission includes a minor change to the indications for use to update new anatomical locations of electrodes (thigh/calf and cervical neck). This change does not constitute any new concerns related to safety and effectiveness as they were designed to be used on body locations that have been previously targeted by traditional electrodes.

Element of Comparison	Primary Predicate K203158 BioWave BioWraps	Subject Device K261522 BioWave BioWraps	Comparison
Compatible TENS Unit/ Neurostimulator	BioWavePRO® RX (K052289) BioWaveHOME® RX (K152437) BioWaveGO® (K180943)	BioWavePRO® RX (K052289) BioWaveHOME® RX (K152437)	Similar. The BioWave BioWraps are no longer used with the BioWaveGo device.
Design (Shape)	Wrappable bands for the hand/wrist, elbow, foot/ankle, knee, and lower back	Wrappable bands for the hand/wrist, elbow, foot/ankle, knee, thigh/calf, cervical neck and lower back	Similar. The current submission includes a minor change to the design to add new anatomical locations that are targeted by the BioWraps (thigh/calf and cervical neck). The differences in design do not raise new questions of safety and effectiveness.
Sterile/ Non-Sterile	Non-Sterile	Non-Sterile	Same
Size	All BioWraps are available in small/medium (S/M) and large/extra-large (L/XL) sizes: Low Back: - *S/M:* 28-38" Waist - *L/XL:* 38-50" Waist Knee: - *S/M:* 12-15.5" circumference around the kneecap - *L/XL:* 15.5 - 19" circumference around the kneecap Foot/Ankle: - *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 Elbow: - *S/M:* 8-12" circumference around the elbow joint with arm extended - *L/XL:* 12-16" circumference around the elbow joint with arm extended Hand/Wrist: - *S/M:* 6-9" circumference around the dominant hand - *L/XL:* 9-12" circumference around the dominant hand	Some BioWraps are available in small/medium (S/M) and large/extra-large (L/XL) sizes, and some are one-size fits all: Low Back: - *S/M:* 28-37" Waist - *L/XL:* 37-50" Waist Knee: - *One size:* 12-24" circumference around the kneecap Foot/Ankle: - *S/M:* Women's shoe size 6-10, Men's shoe size 5-9 - *L/XL:* Women's shoe size 11-16, Men's shoe size 10-15 Elbow: - *S/M:* 8-12" circumference around the elbow joint with arm extended - *L/XL:* 12-16" circumference around the elbow joint with arm extended Hand/Wrist: - *S/M:* 5.75-7" circumference around the dominant hand - *L/XL:* 7-8.5" circumference around the dominant hand Thigh/Calf: - *One size*: 12-30" circumference around the thigh or calf Cervical Neck: - *One size*: 12-20" circumference around the neck	Similar. The current submission includes minor changes to the sizes of the cleared BioWraps to account for design shape updates. This submission also adds new BioWraps for the thigh/calf and cervical neck. The differences in size do not raise new questions of safety and effectiveness. Previously submitted non-clinical testing information supports safety and effectiveness of the 2 new BioWraps in this submission.
	Sizes for the BioWraps are as follows: Low Back:	Sizes for the small/medium and large/extra-large BioWraps are as follows:	Similar. The current submission includes minor changes to the

Element of Comparison	Primary Predicate K203158 BioWave BioWraps	Subject Device K261522 BioWave BioWraps	Comparison
Conductive Surface	- Width: S/M - 4.5"; L/XL – 5.5" - Height: S/M - 3"; L/XL – 3" Knee: - Width in Center: S/M - 3"; L/XL – 3 ½" - Total Height: S/M - 3¼"; L/XL – 4" Foot/Ankle: - Ankle Length: S/M - 11 ½"; L/XL - 13" - Ankle Width: S/M - 1 ¾"; L/XL – 2" - Foot Length: S/M - 9 ½"; L/XL – 10 ½" - Foot Width: S/M - 1 ¾"; L/XL – 2" Elbow: - Width in Center: S/M - 2 1/8"; L/XL – 2 5/8" - Total Height: S/M - 3 ¾"; L/XL – 4 ½" Hand/Wrist: - Hand Width in Center: S/M - 8"; L/XL – 11" - Hand Total Height: S/M – 2 ½"; L/XL – 2 ½" - Wrist Width in Center: S/M - 7"; L/XL – 10" - Wrist Total Height: S/M – 2 ½"; L/XL – 2 ½"	Low Back: - Width: S/M - 4.5"; L/XL – 5.5" - Height: S/M - 3"; L/XL – 3" Knee: - Width in Center: S/M - 3"; L/XL – 3 ½" - Total Height: S/M - 3"; L/XL – 4" Foot/Ankle: - Ankle Length: S/M – 7 ¾"; L/XL – 9 ¾" - Ankle Width: S/M - 1 ½"; L/XL – 2" - Foot Length: S/M - 7 ¾"; L/XL – 9 5/8" - Foot Width: S/M - 1 ½"; L/XL – 2" Elbow: - Width in Center: S/M - 2 ½"; L/XL – 3" - Total Height: S/M - 3 ¾"; L/XL – 4" Hand/Wrist: - Hand Width in Center: S/M – 8.5"; L/XL – 9.5" - Hand Total Height: S/M – 2 ½"; L/XL – 2 ½" - Wrist Width in Center: S/M - 7"; L/XL – 8.5" Wrist Total Height: S/M – 2 ½"; L/XL – 2 ½" Thigh/Calf: - Width in Center: 4¾" - Total Height: 3 ¼" Cervical Neck: - Width in Center: 2" - Total Height: 2 ½"	sizes of the cleared BioWraps to account for design shape updates. This submission also adds new BioWraps for the thigh/calf and cervical neck. The differences in conductive surface size do not raise new questions of safety and effectiveness.
Impedance Parameters	1.27 ohms resistance per inch	1.27 ohms resistance per inch	Same
Washable / Not Washable	Washable	Washable	Same
Reusable	Single Patient, Reusable	Single Patient, Reusable	Same
Patient Contacting	External Only, Intact Skin, <24 Hours Silver Fiber	External Only, Intact Skin, <24 Hours Silver Fiber	Same
Performance Qualities	Bench testing of the conductive fabric confirmed that the garment electrodes do not change their inherent conductivity following washing, indicating that there is no significant adverse effect on conductivity of the device or its inherent ability to deliver low dose current density uniformly to the skin of the wearer.	Bench testing of the conductive fabric submitted under K203158 confirmed that the garment electrodes do not change their inherent conductivity following washing, indicating that there is no significant adverse effect on conductivity of the device or its inherent ability to deliver low dose current density uniformly to the skin of the wearer. This testing applies to the	Same

Element of Comparison	Primary Predicate K203158 BioWave BioWraps	Subject Device K261522 BioWave BioWraps	Comparison
		current device since the conductive material has not changed since review of the predicate.	

Conclusion:

The subject device, which now includes thigh/calf and cervical neck BioWave BioWraps, have the same intended use as the predicate device. The differences between the subject and predicate devices do not raise different questions of safety and effectiveness with respect to indications for use, design, materials, function, availability (i.e., prescription only use), and performance. Therefore, the BioWave BioWraps have been found to be substantially equivalent to the predicate device (BioWave BioWraps, K203158).