February 24, 2021

BioWave Corporation
% Dave Mcgurl
Director, Regulatory Affairs
Mcra LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

Re: K210202
Trade/Device Name: BioWaveGO RX
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: January 12, 2021
Received: January 25, 2021

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, 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,

Jitendra Virani
Acting Assistant Director
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)*
K210202

Device Name
BioWaveGO Rx

Indications for Use *(Describe)*
The BioWaveGO Rx is indicated for prescription use for:
- Symptomatic relief of chronic, intractable pain
- Symptomatic relief of acute pain
- As an adjunctive treatment in the management of post-surgical and post-traumatic acute pain

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

Device Trade Name: BioWaveGO Rx System

Manufacturer:
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Norwalk, CT 06851

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Date Prepared: February 24, 2021

Regulation Number: 21 CFR §882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief

Regulatory Class: II

Product Code: GZJ

Indications for Use:
The BioWaveGO Rx is indicated for prescription use for:

- Symptomatic relief of chronic, intractable pain
- Symptomatic relief of acute pain
- As an adjunctive treatment in the management of post-surgical and post-traumatic acute pain

Device Description:
The BioWaveGO Rx Neuromodulation Pain Therapy Device is a battery-powered device intended to provide pain relief based on the technology of parent devices BioWaveHOME.

The BioWaveGO Rx device delivers the summed high frequency alternating current sinusoidal signals between electrodes, providing symptomatic relief of acute, chronic, and post-operative pain. The device is identical in design to the BioWaveGO cleared in K180943. However, this 510(k) seeks clearance of the device for prescription use. The BioWaveGO Rx has the identical battery and software to the original clearance in K180943.

Predicate Device:
BioWave Corporation's BioWaveGO Neuromodulation Pain Therapy Device is substantially equivalent to the predicates previously cleared with respect to indications, design, function, and materials, as outlined below.

Manufacturer	Device Name	K-Number
BioWave Corporation	BioWaveGO	K180943 (primary predicate)
BioWave Corporation	BioWaveHOME	K152437 (reference device)

Performance Testing Summary:
No additional testing was required for this Special 510(k).

Substantial Equivalence:

The subject device, the BioWaveGO Rx, was demonstrated to be substantially equivalent to the primary predicate device cited in the table above with respect to indications, design, materials, function, manufacturing, and/or performance and to the predicate devices with respect to availability (i.e. prescription) and indications. The subject device is identical in indications and design. The only difference is to make the device available as a prescription use device. There is no additional risk as a healthcare professional would be prescribing the device to the patient.

Predicate Comparison Table

	Subject Device BioWaveGO Rx Device	**Primary Predicate Device** BioWaveGO OTC Device	**Reference Device** BioWaveHOME Device	**Comparison**
Manufacturer	BioWave Corporation	BioWave Corporation	BioWave Corporation	-
Trade Name	BioWaveGO Rx	BioWaveGO	BioWaveHOME	-
510(k)	K210202 (subject)	K180943	K152437	-
Bluetooth Capable	Yes	Yes	No	Identical. Both the primary predicate and subject device have Bluetooth.
Smartphone Interface	Yes	Yes	No	Identical. Both the primary predicate and subject device have a smart phone interface.
Prescription or Over-the-Counter	Prescription	Over-the-Counter	Prescription	Similar. The primary predicate is for OTC use. The reference and subject devices are for prescription use.
Image				-

	Subject Device BioWaveGO Rx Device	**Primary Predicate Device** BioWaveGO OTC Device	**Reference Device** BioWaveHOME Device	**Comparison**
Indications	The BioWaveGO Rx Neuromodulation Pain Therapy Device is indicated for prescription use for: - Symptomatic relief of chronic, intractable pain - Symptomatic relief of acute pain - As an adjunctive treatment in the management of post-surgical and post-traumatic acute pain	The BioWaveGO Neuromodulation Pain Therapy Device is indicated for over-the-counter use for: - Symptomatic relief of chronic, intractable pain - Symptomatic relief of acute pain - As an adjunctive treatment in the management of post-surgical and post-traumatic acute pain	The BioWaveHOME Neuromodulation Pain Therapy Device is indicated for prescription use for: - Symptomatic relief of chronic, intractable pain, post-surgical, and post-traumatic acute pain - Symptomatic relief of acute pain - Symptomatic relief of post-operative pain	Identical. The indications for use are the same as the primary predicate.

Comparison of Basic Unit Characteristics for BioWaveGO RX to BioWaveHOME (K152437) and BioWaveGO (K180943)

	BioWave Corporation BioWaveGO RX Device (Subject)	**BioWave Corporation BioWaveGO Device (K180943)**	**BioWave Corporation BioWaveHOME Device (K152437)**	**Comparison**
Device Name, Model	BioWaveGO Rx	BioWaveGO	BioWaveHOME	-
Manufacturer	BioWave Corporation	BioWave Corporation	BioWave Corporation	-
Power Source(s)	one 3.2V 1100mAh rechargeable lithium iron phosphate battery	one 3.2V 1100mAh rechargeable lithium iron phosphate battery	two 3.2V 3300mAh rechargeable lithium iron phosphate batteries	Identical (BioWaveGO only)
Method of Line Current Isolation	Battery + interlocks	Battery + interlocks	Battery + interlocks	Identical
Patient Leakage Current	None	None	None	Identical
Normal condition	None	None	None	Identical
Single fault condition	None	None	None	Identical
Number of Output Modes	One	One	One	Identical
Number of Output Channels	One	One	One	Identical
Synchronous or Alternating?	N/A	N/A	N/A	-
Method of Channel Isolation	N/A	N/A	N/A	-
Regulated Current or Regulated Voltage?	Regulated Voltage	Regulated Voltage	Regulated Voltage	Identical
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Identical
Automatic Overload Trip?	Yes (software)	Yes (software)	Yes (software)	Identical
Automatic No-Load Trip?	Yes (software)	Yes (software)	Yes (software)	Identical
Automatic Shut Off?	Yes	Yes	Yes	Identical
Patient Override Control?	Yes	Yes	Yes	Identical
Indicator Display:	Yes	Yes	Yes	Identical
On/Off Status?	Yes	Yes	Yes	Identical
Low Battery?	Yes	Yes	Yes	Identical
Voltage/Current Level?	Yes (% of full scale)	Yes (% of full scale)	Yes (% of full scale)	Identical
Timer Range - (minutes)	30	30	30	Identical
Compliance with Voluntary Standards?	Yes	Yes	Yes	Identical
Compliance with 21 CFR 898?	Yes	Yes	Yes	Identical
Weight	6 ounces	6 ounces	1.0 lbs	Identical (BioWaveGO only)

	BioWave Corporation BioWaveGO RX Device (Subject)	BioWave Corporation BioWaveGO Device (K180943)	BioWave Corporation BioWaveHOME Device (K152437)	Comparison
Dimensions (in.) (W x H x D)	3.0" x"4.0" x 1.0"	3.0" x"4.0" x 1.0"	3.75" x 6.0" x 1.75"	Identical (BioWaveGO only)
Housing Materials and Construction	ABS via conventional injection molding	ABS via conventional injection molding	ABS via conventional injection molding	Identical

Comparison of Output Specifications for BioWaveGO Rx to BioWaveHOME (K152437) and BioWaveGO (K180943)

	BioWave Corporation BioWaveGO Rx Device (Subject)	BioWave Corporation BioWaveGO Device (K180943)	Parent BioWave Corporation BioWaveHOME Device (K152437)	Comparison
Waveform	Biphasic	Biphasic	Biphasic	Identical
Shape	Sum of 2 sine waves	Sum of 2 sine waves	Sum of 2 sine waves	Identical
Maximum Output Voltage Available (+1-2%) (with software calibration correction)	80V p-p @ 500 Ω 20 V AC RMS	80V p-p @ 500 Ω 20 V AC RMS	110V p-p @ 500 Ω 27.5 V AC RMS	Identical (BioWaveGO only) BioWaveGO Rx offers a decreased maximum voltage compared to BioWaveHOME
Maximum Output Current (+1- 2 %) (current depends on load)	160mA p-p @ 500 Ω 40mA RMS 40 mA p-p @ 2kΩ Trip out @ 10kΩ	160mA p-p @ 500 Ω 40mA RMS 40 mA p-p @ 2kΩ Trip out @ 10kΩ	220mA p-p @ 500 Ω 55mA RMS 55 mA p-p @ 2kΩ Trip out @ 10kΩ	Identical (BioWaveGO only) BioWaveGO Rx has a lower maximum current density compared to BioWaveHOME.
Pulse Width	Continuous modulation	Continuous modulation	Continuous modulation	Identical
Frequency (Hz)	4062 Hz + 3940 Hz	4062 Hz + 3940 Hz	3980 Hz + 3858 Hz	Equivalence based on frequency difference
For interferential modes only: **- Beat Frequency (Hz)**	122 Hz	122 Hz	122 Hz	Identical
For multiphasic waveforms only: **- Symmetrical phases?** **- Phase Duration**	N/A N/A	N/A N/A	N/A N/A	-

	BioWave Corporation BioWaveGO Rx Device (Subject)	**BioWave Corporation BioWaveGO Device (K180943)**	**Parent BioWave Corporation BioWaveHOME Device (K152437)**	**Comparison**
Net Charge (m C per pulse) (If zero, state method of achieving zero net charge.)	0 @ 500 Ω biphasic – AC coupled continuous wave	0 @ 500 Ω biphasic – AC coupled continuous wave	0 @ 500 Ω biphasic – AC coupled continuous wave	Identical
Maximum Phase Charge, (µ C)	N/A	N/A	N/A	-
Maximum Current Density, (µmA/cm^2) (with 1.375" diam pad = 9.58 cm2 area)	6.9 ma rms per cm^2 @ 500 Ω	6.9 ma rms per cm^2 @ 500 Ω	6.9 ma rms per cm^2 @ 500 Ω	Identical
Maximum Power Density, (W/cm^2) (using 1.375" diam 9.58 cm^2 electrode conductive surface area)	0.19 W rms per cm^2 @ 500 Ω	0.19 W rms per cm^2 @ 500 Ω	0.19 W rms per cm^2 @ 500 Ω	Identical
Burst Mode **a. Pulses per burst** **b. Bursts per second** **c. Burst duration (seconds)** **d. Duty Cycle [Line (b) x Line (c)]**	N/A	N/A	N/A	-
ON Time (seconds)	N/A	N/A	N/A	-
OFF Time (seconds)	N/A	N/A	N/A	-
Additional Features (if applicable)	Many safety interlocks: cable connected to unit, pads connected to cable, pads connected to body, max power density, battery ok for treatment, charger connected (trip off)	Many safety interlocks: cable connected to unit, pads connected to cable, pads connected to body, max power density, battery ok for treatment, charger connected (trip off)	Many safety interlocks: cable connected to unit, pads connected to cable, pads connected to body, max power density, battery ok for treatment, charger connected (trip off)	Identical

Conclusion:

The BioWaveGO Rx device has been found to be substantially equivalent to the previously cleared predicate device, BioWaveGO, with respect to its intended use, design, function, materials, and performance.