August 17, 2018

Biowave Corporation
% Dave Mcgurl
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA)
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K180943
Trade/Device Name: BioWaveGO
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, GZJ
Dated: July 11, 2018
Received: July 11, 2018

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. 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,

Carlos L. Pena -S

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)*
K180943

Device Name
BioWaveGo

Indications for Use *(Describe)*
The BioWaveGO Neuromodulation Pain Therapy Device is indicated 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.

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510(K) SUMMARY

K180943

Device Trade Name: BioWaveGO System

Manufacturer:
BioWave Corporation
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Norwalk, CT 06851

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Date Prepared: April 26th, 2018

Classifications: 21 CFR §882.5890, Transcutaneous electrical nerve stimulator for pain relief

Class: II

Product Codes: NUH, GZJ

Indications For Use:
The BioWaveGO Neuromodulation Pain Therapy is indicated 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 Neuromodulation Pain Therapy Device is a battery-powered device intended to provide pain relief based on the technology of parent devices BioWaveHOME and BioWavePRO. The key difference between the BioWaveGO and the parent device, the BioWaveHOME, is a reduced maximum voltage level, making the device available over-the-counter. The BioWaveGO device has a smaller battery system compared to the BioWaveHOME device. The BioWaveGO device delivers the summed high frequency alternating current sinusoidal signals between electrodes, providing symptomatic relief of acute, chronic, and post-operative pain.

Predicate Device:
The 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 (primary predicate)	BioWaveHOME	K152437
NeuroMetrix, Inc. (reference device)	Quell	K152954
Fuji Dynamics Ltd. (reference device)	LL TENS 160A, LL TENS 160B	K152374

Performance Testing Summary:
The testing of the BioWaveGO device and the smartphone app includes:

- Testing of basic operational modes to confirm that the session timer is only operational during active treatment time.
- Battery testing to ensure charging only occurs when the device is not in use and that active treatment sessions cannot be started during charging.
- Testing to ensure consistent operation across various intensities and load impedances.
- Testing to ensure recognition of the cable and electrodes before and during an active session.
- Testing to ensure invalid load impendences are detected before and during an active session.
- Abuse of the battery charger input and output ports testing to determine if damage to the device or improper software operation occurs.
- Testing in over-temperature situations to determine if the inherent protection mechanisms protect draw on the battery outside safe operating temperatures.
- Testing to determine if the hardware watchdog timers were functional at resetting the device.
- Evaluation of electrical safety.

Substantial Equivalence:

Predicate Comparison Table

	Subject Device BioWaveGO Device	**Predicate Device** BioWaveHOME Device	**Reference Device** Quell
Manufacturer	BioWave Corporation	BioWave Corporation	Neurometrix, Inc.
Trade Name	BioWaveGO	BioWaveHOME	Quell
510(k)	K180943	K152437	K152954
Bluetooth Capable	Yes	No	Yes
Smartphone Interface	Yes	No	Yes
Prescription or Over-the-Counter	Over-the-Counter	Prescription	Over-the-Counter

	Subject Device BioWaveGO Device	**Predicate Device** BioWaveHOME Device	**Reference Device** Quell
Image			
Indications	The BioWaveGO Neuromodulation Pain Therapy Device is indicated 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	The BioWaveHOME Neuromodulation Pain Therapy Device is indicated 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	Quell is intended for use as a transcutaneous electrical nerve stimulation device for the symptomatic relief and management of chronic intractable pain. The device may be used during sleep. The device is labeled for use only with compatible NeuroMetrix electrodes.

Comparison of Basic Unit Characteristics for BioWaveHOME and BioWaveGO

	BioWave Corporation BioWaveGO Device	BioWave Corporation BioWaveHOME Device	Comparison of BioWaveGO and BioWaveHOME
510(k) Number	K180943	K152437	-
Device Name, Model	BioWaveGO	BioWaveHOME	-
Manufacturer	BioWave Corporation	BioWave Corporation	Identical
Availability	Over-the-Counter	Prescription	BioWaveGO is designed as an over-the-counter neuromodulation pain therapy device sharing identical specifications to the parent device, BioWaveHOME, with the exception of a decreased maximum voltage (20V versus 27.5V)
Power Source(s)	one 3.2V 1100mAh rechargeable lithium iron phosphate battery	two 3.2V 3300mAh rechargeable lithium iron phosphate batteries	Similar power source but a smaller battery system in BioWaveGO vs BioWaveHOME
Method of Line Current Isolation	Battery + interlocks	Battery + interlocks	Identical
Patient Leakage Current	None	None	Identical
Normal condition	None	None	Identical
Single fault condition	None	None	Identical
Number of Output Modes	One	One	Identical
Number of Output Channels	One	One	Identical
Synchronous or Alternating?	N/A	N/A	-
Method of Channel Isolation	N/A	N/A	-
Regulated Current or Regulated Voltage?	Regulated Voltage	Regulated Voltage	Identical
Software/Firmware/Microprocessor Control?	Yes	Yes	Identical
Automatic Overload Trip?	Yes (software)	Yes (software)	Identical
Automatic No-Load Trip?	Yes (software)	Yes (software)	Identical
Automatic Shut Off?	Yes	Yes	Identical
Patient Override Control?	Yes	Yes	Identical
Indicator Display:	Yes	Yes	Identical
On/Off Status?	Yes	Yes	Identical
Low Battery?	Yes	Yes	Identical
Voltage/Current Level?	Yes (% of full scale)	Yes (% of full scale)	Identical
Timer Range - (minutes)	30	30	Identical
Compliance with Voluntary Standards?	Yes	Yes	Identical

	BioWave Corporation BioWaveGO Device	BioWave Corporation BioWaveHOME Device	Comparison of BioWaveGO and BioWaveHOME
Compliance with 21 CFR 898?	Yes	Yes	Identical
Weight	6 ounces	1.0 lbs	BioWaveGO is lighter
Dimensions (in.) (W x H x D)	3.0" x"4.0" x 1.0"	3.75" x 6.0" x 1.75"	BioWaveGO is smaller
Housing Materials and Construction	ABS via conventional injection molding	ABS via conventional injection molding	Identical

Comparison of Output Specifications for BioWaveHOME and BioWaveGO

	BioWave Corporation BioWaveGO Device	Parent BioWave Corporation BioWaveHOME Device	Comparison of BioWaveGO and BioWaveHOME
Waveform	Biphasic	Biphasic	Identical
Shape	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	110V p-p @ 500 Ω 27.5 V AC RMS	BioWaveGO offers a decreased maximum voltage to allow for over-the-counter availability. The decrease in voltage does not impact safety or performance of the device.
Maximum Output Current(+1- 2 %) (current depends on load)	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	BioWaveGO has a lower maximum current density.
Pulse Width	Continuous modulation	Continuous modulation	Identical
For multiphasic waveforms only: **- Symmetrical phases?** **- Phase Duration**	 N/A N/A	 N/A N/A	-
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	Identical
Maximum Phase Charge, (µ C)	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	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	Identical
Burst Mode **a. Pulses per burst** **b. Bursts per second** **c. Burst duration (seconds)**	N/A	N/A	-

	BioWave Corporation BioWaveGO Device	Parent BioWave Corporation BioWaveHOME Device	Comparison of BioWaveGO and BioWaveHOME
d. Duty Cycle [Line (b) x Line (c)]			
ON Time (seconds)	N/A	N/A	-
OFF Time (seconds)	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)	Identical

The subject device, the BioWaveGO, was demonstrated to be substantially equivalent to predicate device K152437 cited in the table above with respect to design, materials, function, manufacturing, and/or performance and to the reference devices (K152374 and K152954) with respect to IFU and over-the-counter use.

Conclusion:

The BioWaveGO device has been found to be substantially equivalent to the previously cleared predicate device, BioWaveHOME (K152437), with respect to its design, function, materials, and performance, and the reference devices, LL TENS 160A, LL TENS 160B (K152374) and Quell (K152954) with respect to indications for use and over-the-counter availability.