July 18, 2019

Medical Currents Ltd
% Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania 10
Rome, 00153 It

Re: K182794
Trade/Device Name: BionicGym Powered Muscle Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June 14, 2019
Received: June 19, 2019

Dear Roger Gray:

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,

Vivek Pinto, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182794

Device Name
BionicGym Powered Muscle Stimulator

Indications for Use *(Describe)*
BionicGym is intended to stimulate healthy muscles in order to exercise, improve or facilitate muscle performance. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles.

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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MEDICAL CURRENTS LTD

bionicGYM

510(k) Summary

I. General Information on Submitter

Submitter/Address:	Medical Currents Ltd 8 Cuffe Lane Dublin 2 D02W840 Ireland
Contact person:	Dr. Louis Crowe
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Correspondent:	Mr. Roger Gray VP, Quality and Regulatory Donawa Lifescience Consulting Srl Piazza Albania 10 00153 Rome Italy
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II. Date Prepared

17 July 2019

III. General Information on Device

Device Name:	BionicGym Powered Muscle Stimulator
Common Name:	Powered Muscle Stimulator
Regulation Number:	21 CFR 890.5850
Regulation Name:	Stimulator, muscle, powered, for muscle conditioning
Product Code:	NGX
Regulatory Class:	II

IV. Predicate Devices

PowerDot® PD-01 Muscle Stimulator (K150078). The predicate device has not been subject to any design related recalls.

V. Device Description

The BionicGym Powered Muscle Stimulator is a home use, wearable device in the form of a double thigh wrap garment. The electronics are housed in a control unit that is fitted into a pocket on the right thigh garment. The control unit generates electrical pulses which are distributed to hydrogel electrodes positioned within the thigh garments and in contact with the user's thighs. The control unit delivers pulses to the muscles via the electrodes in defined patterns, which cause controlled contractions of the legs. The program characteristics determine the leg muscle contractions, which may be tetanic or sub-tetanic, the latter of which can induce cardiovascular and aerobic demand, thus the user receives an exercise workout. The intensity of the workout can be selected from a suite available via a smart device (e.g. phone) based application ('App'). The workout can be paused or stopped from either the App or the control unit.

The principle of operation of the BionicGym Powered Muscle Stimulator is that the pulse pattern delivered to the thigh electrodes is a composite of pulses shared between the electrode array. Repeating the pulse pattern induces contractions of the large muscle groups in the legs (quadriceps, hamstrings, gluteal and calf muscles), exercising the legs and raising the user's heart rate.

BionicGym can run a variety of training programs. However, there is a hard-limit in the firmware of 140 V and 200 mA maximum pulse amplitude, and the electrodes are large (≥150 x100 mm), so the pulse/current density is always low and the maximum amplitudes are always within allowable limits.

Wireless communication is used to control the workout programs, utilizing Bluetooth for communications between the control unit, thigh wrap electrodes, and Smartphone App. The Smartphone App is available for both Android and iPhone operating systems.

VI. Indications for Use

BionicGym is intended to stimulate healthy muscles in order to exercise, improve or facilitate muscle performance. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles.

VII. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices

The Indications for Use for BionicGym are very similar to those for the predicate device. While the predicate device is intended to be applied to a number of muscle groups, BionicGym is intended for application to the wearer's thighs.

Both the subject and predicate devices are controlled via a Smartphone App, which communicates with the unit controller via low energy Bluetooth. Both subject and predicate devices use electronic pulses to stimulate the muscles to which they are applied, with a number of programmable variants.

Differences exist between the subject and predicate device in relation to the nature, strength and duration of the stimulation pulses, but these differences are not significant in relation to the safety and effectiveness of the devices.

Table 1 includes a detailed comparison between the subject and predicate devices.

Table 1: Predicate device comparison table

Item	Subject device	Predicate Device (PD)	Similarity
Device name	BionicGym Powered Muscle Stimulator	PowerDot® PD-01 Muscle Stimulator	N/A
510(k) Sponsor	Medical Currents Ltd, Ireland	Smartmissimo Technologies Pte Ltd, Singapore	N/A
510(k) Reference	Not yet assigned	K150078	N/A
FDA Product Code	NGX	NGX	Same
FDA Classification Name	Stimulator, muscle, powered, for muscle conditioning	Stimulator, muscle, powered, for muscle conditioning	Same
FDA Regulation Number	21 CFR 890.5850	21 CFR 890.5850	Same
Device description	A wearable device in the form of a two thigh wraps. The electronics are housed in a control unit which generates electrical pulses which are distributed to hydrogel electrodes positioned within the thigh garments. Designed to be used with the BionicGym Mobile App.	The PD-01 Muscle Stimulator is a battery-powered neuromuscular stimulator intended to be used with the PowerDot® Mobile Application. PowerDot® electrodes can be applied to multiple anatomical sites.	Substantially Equivalent

Table 1: Predicate device comparison table			
Item	**Subject device**	**Predicate Device (PD)**	**Similarity**
Indications for Use	BionicGym is intended to stimulate healthy muscles in order to exercise, improve or facilitate muscle performance. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles.	The PowerDot PD-01 device, used with PowerDot Mobile Application, is intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance. The PowerDot PD-01 device and PowerDot Mobile Application are not intended to be used in conjunction with therapy or treatment diseases of medical or medical conditions of any kind.	Substantially Equivalent
Rx / OTC?	OTC	OTC	Same
Electrical safety	Complies with: IEC 60601-1 IEC 60601-1-11 IEC 60601-2-10	Complies with: IEC 60601-1 IEC 60601-1-11 IEC 60601-2-10	Same
Electromagnetic compatibility	Complies with: IEC 60601-1-2	Complies with: IEC 60601-1-2	Same
Anatomical sites	Thighs	Multiple	Different
Power Source	2 x Battery, Li-Po, rechargeable. Not replaceable by user.	Battery, Li-Po, rechargeable. Not replaceable by user.	Same
Method of Line Current Isolation	N/A	N/A	Same
Patient Leakage Current	Normal: < 25 µA Single fault: < 25 µA	Normal: < 25 µA Single fault: < 25 µA	Same
Average DC current through electrodes when device is on but no pulses are being applied	0 µA	0 µA	Same
Number of output modes	One output mode, but with varying stimulation parameters	One output mode, but with varying stimulation frequency, pulse width and duty cycle ranges	Substantially Equivalent
Number of output channels	Any combination of 8 electrodes can form a channel (synchronous)	2 channels Synchronous (with asynchronous support)	Different
Method of channel isolation	Galvanic	Galvanic	Same
Regulated current or voltage	Regulated current within allowable voltage range	Regulated voltage	Different
Microprocessor controlled	Yes	Yes	Same
Automatic overload trip	Yes	Yes	Same
Automatic no-load trip	Yes	Yes	Same
Automatic shut-off	Yes	Yes	Same
User over-ride control	Yes	Yes	Same
Indicator display: - On/Off status -Low battery - Voltage/ current level	 Yes Yes Yes (as 'intensity')	 Yes Yes Yes	Same
Timer range	0 - 120 mins max	0 - 60 mins max	Different
Compliance with 21 CFR 898	Yes	Yes	Same

Table 1: Predicate device comparison table			
Item	**Subject device**	**Predicate Device (PD)**	**Similarity**
Waveform	Biphasic rectangular symmetrical with charge balancing second phase, Zero net DC	Biphasic, close to rectangular, asymmetrical, with charge balancing second phase, zero net DC	Different
Maximum Output Voltage (+/- 15 %)	140 V @ 500 Ω 140 V @ 2 kΩ 140 V @ 10 kΩ	90 V @ 500 Ω 122 V @ 2 kΩ 138 V @ 10 kΩ	Substantially Equivalent
Maximum Output Current (+/- 15 %)	*At pulse width of 400 µs:* 200 mA @ 500 Ω 70 mA @ 2 kΩ 14 mA @ 10 kΩ	*At pulse width of 400 µs:* 136 mA @ 500 Ω 50 mA @ 2 kΩ 12.4 mA @ 10 kΩ	Substantially Equivalent
Pulse width	10 µs to 400 µs	150-400 µs (for main phase)	Substantially Equivalent
Frequency	1 - 99 Hz per channel	1 - 120 Hz	Different
For interferential modes only: - Beat Frequency (Hz)	N/A	N/A	Same
For multiphasic waveforms only: - Symmetrical phases - Phase duration(s)	Yes 1 µs to 400 µs for positive phase, same for negative phase	No 150-400 µs for positive phase, same for negative phase	Substantially Equivalent
Net charge How achieved	0 µC at 500 Ω Symmetrical pulses	0 µC at 500 Ω Capacitor coupling	Different
Maximum phase charge (@ 500 Ω), µC per pulse	80 µC	34.4 µC	Substantially Equivalent
Maximum current density (@ 500 Ω), mA/cm^2 (rms)	0.50 mA/cm^2	1.27 mA/cm^2	Different
Maximum average current, mA (@ 500 Ω) (average absolute value)	9.9 mA	2.7 mA	Different
Maximum average power density, W/cm^2 (@ 500 Ω)	0.0100 W/cm^2	0.0177 W/cm^2	Different
Burst mode: a) Pulses per second b) Bursts per second c) Burst duration d) Duty Cycle: = (b) x (c)	N/A	a) 2 b) 120 c) 150-400 µs d) 2-12 x 2-60	Different
ON Time	Continuous or 0.1 to 24 sec	Continuous or 2-12 sec	Substantially Equivalent
OFF Time	0-120 sec	0-60 sec	Substantially Equivalent
Electrode type	Self adhesive	Self adhesive	Same
Electrode dimensions	168 x 112 x 2.4 mm	8 x 4 cm and 4.5 cm diameter	Different
Electrode weight	57 g	Unknown	Different
Electrode conductive surface area	175 cm^2	Approx 30 cm^2 and 15 cm^2	Different

Table 1: Predicate device comparison table			
Item	**Subject device**	**Predicate Device (PD)**	**Similarity**
Electrodes in use during exercise session	2 - 8	1 or 2	Different
Electrode materials	• Silicone-coated PET release liner • Hydrogel reference G607 • Conductive carbon film • Printed silver pattern on the carbon film	• MultiStick® MG-1500 hydrogel • Other materials unknown	Different
Incorporated electroconductive media?	Yes	Yes	Same
Electrode hydrogel pH	5.3 to 5.5	Unknown	Probably equivalent
Hydrogel formulation	Glycerine 60% Polyacrylic acid 20% Water 19% Salt 1%	Unknown	Probably equivalent
Skin-to-electrode Impedance Range	310 to 451 Ω	Unknown	Unknown
Maximum duration of electrode use	25 workout sessions	Single workout session	Different
Secondary electrode support?	Yes - thigh wraps	No	Different
Wrap dimensions	Large – R Leg 647 x 376 x 20 mm Large – L Leg 647 x 376 x 16 mm Small – R Leg 567 x 347 x 20 mm Small – L Leg 567 x 347 x 16 mm Extension 225 x 130 x 1.5 mm	N/A	N/A
Wrap weight	Large – R Leg 284 g Large – L Leg 266 g Small – R Leg 242 g Small – L Leg 234 g Extension 67 g	N/A	N/A
Wrap material	Neoprene and nylon/spandex blend	N/A	N/A
Smartphone App?	Yes	Yes	Same

The subject device and the predicate devices have many identical or similar properties or features. The differences that exist with respect to device functionality are:

- BionicGym includes thigh wraps with predefined electrode positions, whereas the predicate device electrodes can be placed in many different locations.
- The BionicGym electrodes are much larger, resulting in lower current density at maximum output.
- BionicGym incorporates an electrode check in the software to ensure all active electrodes are in appropriate contact with the skin; no such check is present in the predicate device.
- BionicGym has known electrode positions and does not allow the user to determine relative channel intensities and/or positions. The user picks from a suite of known and tested programs with pre-determined channels and relative channel intensities.
- BionicGym pulses are symmetrical biphasic, as opposed to asymmetrical biphasic in the predicate).
- The user can choose a program lasting up to two hours, (as opposed to one hour in the predicate).
- BionicGym uses thigh wraps to allow correct positioning and support of the electrodes, whereas the predicate has no secondary means of support for the electrodes.

With regard to these differences, the following paragraphs provide additional explanations:

Anatomical sites: BionicGym can be used only on the thighs. The thigh wraps cannot be fitted around the head, neck or torso, thus the possibility of inadvertent transcerebral, carotid sinus or transthoracic stimulation pathways is avoided by design.

Number of output channels: The predicate device has only two channels, which limits the muscles it can target. For instance, from the website for the predicate, it appears the device can target only the quadriceps OR hamstring of only one leg at a time. By using more channels, BionicGym allows each muscle group to receive similar and balanced contractions and overall exercise times.

Timer range: It is often the case that exercise sessions last for longer than an hour, as allowed by the predicate device. BionicGym allows sessions to last up to two hours, which is not significant in safety terms, because the current densities through the skin are low when compared with the predicate device.

Regulated current or voltage: With regulated current, as used in BionicGym, the exact pulse put into the user body is known, with an assurance of there being no net DC. Furthermore, the output is limited to 140 V (substantially less than the 500 V maximal permissible voltage).

Waveform: The BionicGym waveform is symmetrical, compared with the predicate device, which has an asymmetrical waveform. Having a symmetrical waveform helps ensure no net DC.

Net Charge: how achieved: Symmetrical biphasic pulses are used in BionicGym, whereas capacitive coupling is used in the predicate device. In BionicGym, each phase balances each other in shape as well as intensity and duration. As a further safety feature, each pulse is 'reversed' every second time it is given. E.g. if pulse 1 has electrode A positive and electrode B negative (in the first phase of the biphasic pulse) the next time it is delivered it will lead with A negative and B positive, etc. Thus, if there is any imbalance in a given pulse, the Net Charge would still be minimized when averaged over two of the pulses.

Maximum Current Density; Maximum Average Current; Maximum Average Power Density: These three parameters are closely related. BionicGym uses 8 electrodes that are each larger than the combined surface area of the 4 electrodes in the predicate device. This ensures that BionicGym delivers stimulation (up to the permissible level of 10 mA) while always maintaining a low current density and low power density.

Burst Mode: BionicGym does not have a burst mode, whereas the predicate device does.

Electrodes in use during exercise session: BionicGym has 8, while the predicate device has 4. BionicGym can contract both legs simultaneously, whereas the predicate can contract only a part of one leg at a time. Thus, BionicGym can achieve more balanced contractions, and both legs receive similar exercise levels and duration.

Thigh wraps: The BionicGym thigh wraps provide secondary support for the self adhesive electrodes, whereas the predicate relies on the self adhesive nature of the electrodes for conductivity. This secondary support in the BionicGym allows reuse of the electrodes up to 25 times, whereas the predicate device electrodes are intended for single use only.

None of the above-identified differences have any adverse effect on the safety or effectiveness of the subject device when compared with the predicate.

VIII. Summary of Non-Clinical Performance Testing

BionicGym has been subjected to non-clinical performance testing as follows:

Electrical safety:

- IEC 60601-1:2005+AMD1:2012, 'Medical electrical equipment - Part 1: General requirements for basic safety and essential performance'

- IEC 60601-1-2:2012, 'Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests'
- IEC 60601-1-11:2015, 'Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment'

Electromagnetic compatibility:
- IEC 60601-2-10:2012+AMD1:2016, 'Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators'

Biocompatibility:
BionicGym components that contact the wearer are the thigh pad garments and the gel electrodes. Testing has demonstrated compliance with the following biocompatibility standards, based on these components being 'surface devices' with 'prolonged' contact with intact skin, in accordance with FDA guidance 'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"', and ISO 10993-1 'Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process':

- ISO 10993-5: 2009, 'Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity'
- ISO 10993-10:2010, 'Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization'

Software verification and validation testing:
The software has been developed, verified, validated and documented in accordance with FDA guidance, including:

- 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices', 11 May 2005.
- 'General Principles of Software Validation; Final Guidance for Industry and FDA Staff', 11 January 2002.
- 'Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices', 9 September 1999.
- 'Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff', October 2, 2014.
- 'Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software', 14 January 2005.
- 'Postmarket Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff', 28 December 2016.

The software in BionicGym is in three parts:

- BionicGym Firmware (control unit (MCU) and Bluetooth low energy system on chip (BLE SoC)) (Moderate level of concern)
- BionicGym Application (App) running on a Smartphone (Moderate level of concern)
- BionicGym Web Application (Minor level of concern)

Bench tests:

- Control Unit Assembly and Test
- PSU and Dock Assembly and Test
- Control Unit Free Fall and Impact Tests
- Garment Impact Tests
- Simulated Transport Tests
- Battery Charging Tests
- Aging Tests
- Reusability Tests

- Maximum Power Density Test

IX. Conclusion

The subject and predicate devices have the same intended use and fundamental technological characteristics. The differences in technological characteristics between subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.