DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 30, 2015

Smartmissimo Technologies Pte Ltd
Alexey Pisarev
Chief Executive Officer
#28-01, Sgx Centre II, 4 Shenton Way
Singapore, 068807 SG

Re: K150078
Trade/Device Name: PowerDot Pd-01 Muscle Stimulator (with PowerDot Mobile Application)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: August 18, 2015
Received: August 31, 2015

Dear Alexey Pisarev:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -S

for 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150078

Device Name
PowerDot® PD-01 Muscle Stimulator (with PowerDot® Mobile Application)

Indications for Use *(Describe)*
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.

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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5. 510(k) Summary

This summary is being submitted in accordance with the requirements of 21 CFR 807.92.

5.1 Submitter

Smartmissimo Technologies Pte Ltd.
4 Shenton Way, #28-01 SGX Centre II,
Singapore, 068807

Contact: Alexey Pisarev, Chief Executive Officer
Tel. +65 83216256
Email: alexey@getpowerdot.com

5.2 Date Prepared: Sept 29, 2015

5.3 Device Name and Classification Information:

Trade/Proprietary Name: PowerDot® PD-01 Muscle Stimulator (with PowerDot® Mobile Application)
Common Name: Smart Wearable Sports Muscle Stimulator
Classification Name: Powered Muscle Stimulator for Muscle Conditioning
Classification: 21 CFR 890.5850, Class II
Product Code: NGX
Panel: 89, Physical Medicine

5.4 Predicate Device: Compex® Sport Plus (K083140)

5.5 Device Description:

PowerDot PD-01 Muscle Stimulator is a battery-powered neuromuscular stimulator intended to stimulate healthy muscles in order to improve or facilitate muscle performance and, with that regard, may be considered a technique or method for muscle training.

PowerDot PD-01 device is designed to be used together with PowerDot Mobile Application.

PowerDot PD-01 device uses Bluetooth™ Low Energy (Bluetooth 4.0, Class II) wireless radio frequency protocol for communication with supported range of mobile devices (such as smartphones and/or tablets) via PowerDot Mobile Application.

Accessories include lead cables of 2 different lengths, USB charging cable, 2 types of hydrogel-based self-adhesive electrode pads and carrying case.

5.6 Indications for Use:

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.

5.7 Contraindications

PowerDot PD-01 device and PowerDot Mobile Application should not be used by anyone with a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

5.8 Brief Technical Comparison with the Predicate Device and Discussion of Differences

Parameter	PowerDot PD-01 (with PowerDot Mobile Application)	Compex Sport Plus (K083140)	Substantial Equivalence
Intended Use and Indications For Use	The PowerDot PD-01 device 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.	Intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance. Compex Sport is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. Usage of any of Compex Sport programs on injured or ailing muscles is contraindicated.	Same
Use environment	Over-the-counter (non-prescriptive) use in athletic training facilities or at home	Over-the-counter (non-prescriptive) use in athletic training facilities or at home	Same
Anatomical Sites	Electrodes can be applied to multiple anatomical sites.	Electrodes can be applied to multiple anatomical sites.	Same
Stimulation Parameters			
Power Source **Method of Line Current Isolation**	Battery, Li-Po, rechargeable. Not replaceable by user. N/A	Battery, Ni-MH, rechargeable N/A	Substantially equivalent. Both devices are powered with rechargeable batteries.
Patient Leakage Current - **Normal Condition** - **Single Fault Condition**	< 25 µA < 25 µA	Unknown Unknown	Unable to compare. Leakage current of PowerDot PD-01 is extremely low and meets IEC 60601-1 safety criteria.
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	One output mode, but	Substantially

	varying stimulation frequency, pulse width and duty cycle ranges	with varying stimulation frequency and duty cycle ranges	equivalent
Number of output channels	2 channels (or 4 channels when two PowerDot PD-01 devices are used with one PowerDot Mobile Application application)	4 channels	Substantially equivalent.
Synchronous or alternating	Synchronous (with asynchronous support)	Synchronous	
Method of channel isolation	Galvanic	Galvanic	Substantially equivalent
Regulated current or regulated voltage	Regulated voltage	Regulated current	Substantially equivalent. Difference is regulation technology is not substantial as both technologies are efficient for power output control.
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**	Yes	Yes	Same
- **Low battery**	Yes (available from PowerDot Mobile Application)	Yes	Substantially equivalent. PowerDot and Compex indicators serve the same purpose.
- **Voltage/current level**	Yes (available from PowerDot Mobile Application)	Yes	
Timer range in minutes	60 minutes maximum (for the longest running 'Endurance' program possible)	Maximum program: 60 minutes	Substantially equivalent. Both devices can be used for extended periods of time.
Compliance with voluntary standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Substantially equivalent
Compliance with 21 CFR 898	Yes	Yes	Same
Weight	0.5 oz/25 g	12.5 oz/350 g	Substantially

			equivalent. Both devices are small and lightweight.
Dimensions	2.4”x1.7”x0.5”	5.6”x1.5”x3.9”	Substantially equivalent
Housing material and construction	Plastic injection molding, TPU	Plastic injection molding	Substantially equivalent PowerDot housing materials are evaluated for biocompatibility.

5.9 Non-clinical Tests

The following non-clinical testing was provided in this 510(k):

Biocompatibility Testing

Skin contacting hydrogel, which is used in PowerDot electrode pads, has been tested to ISO 10993-1:2009 standard.

TPU, ABS and PVC Compound materials, used in PowerDot PD-01 device housing and lead cables, were evaluated for biocompatibility based on Material Safety Data Sheets provided by the material vendors, and were concluded to be safe and biocompatible.

Software Verification and Validation

PowerDot Firmware and PowerDot Mobile Application software documentation, consistent with a moderate level of concern, is provided with this 510(k).

System Validation Testing proves that all software requirement specifications were met and all software hazards were mitigated to Accepted risk level.

Electrical Safety and Electromagnetic Compatibility Testing

PowerDot PD-01 device together with its controlling PowerDot Mobile Application has been designed to comply and tested for compatibility with the applicable clauses of the following FDA-recognized standards:

- IEC/EN 60601-1:2005 “Medical Electrical Equipment - Part 1: General Requirements for Safety”
- IEC 60601-2-10:2012 “Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators. Edition 2.0”

- IEC/EN 60601-1-2:2014 “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Disturbances - Requirements and tests. Edition 4.0”

- IEC/EN 60601-1-11:2010 “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. Edition 1.0”

Battery Testing

Lithium-Polymer battery, used in PowerDot PD-01 was tested by battery manufacturer for compliance with FDA-recognized UL 1642 Standard for Lithium Batteries (Cells).

Engineering Bench Testing

In addition to the full system validation testing, the 510(k) also included testing in accordance with the recommendations of FDA's "*Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Powered Muscle Stimulator for Muscle Conditioning*", Attachment 11, Section 1 - Output Waveforms. Oscilloscope tracings were obtained of the device output waveforms under maximum supported voltage and pulse widths under loads of 500 Ω, 2 kΩ and 10 kΩ.

Also, a number of system validation testing scenarios covering mitigation of wireless risks in accordance with FDA’s “*Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff*” were added to our full system testing protocol.

5.10 Brief Description of clinical performance data

No applicable. This device does not diagnose, cure, mitigate, treat or prevent disease or affect the function of the human body.

Clinical effectiveness of the device was based on a literature review.

5.11 Conclusion

Test results demonstrate the PowerDot PD-01 device with PowerDot Mobile Application is safe and effective for its intended use and the results support determination of substantial equivalent.

The usage of PowerDot Mobile Application as a wireless user interface for PowerDot PD-01 device as well as any other engineering differences do not: (1) affect the intended use (2) alter the fundamental scientific technology of the device.