DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 1, 2016

Bio-Medical Research Ltd
Anne-Marie Keenan
Regulatory Affairs Specialist
Parkmore Business Park West
Galway, H91 NHT7 Ireland

Re: K161974
Trade/Device Name: SLENDERTONE® Connect Abs, Type 570
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 3, 2016
Received: October 5, 2016

Dear Anne-Marie Keenan:

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,

Michael J. Hoffmann -A

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)*
K161974

Device Name
SLENDERTONE® Connect Abs, Type 570

Indications for Use *(Describe)*
The SLENDERTONE® Connect Abs, Type 570 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is indicated for the improvement of abdominal muscle tone, for the strengthening of the abdominal muscles and for the development of a firmer abdomen.

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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510k SUMMARY
K161974

I. SUBMITTER	
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Prepared:	July 14, 2016
II. DEVICE	
Trade Name of Device:	SLENDERTONE® Connect Abs, Type 570
Common Name:	Powered muscle stimulator
Regulation Number:	21 CFR 890.5850
Regulation Description:	Stimulator, muscle, powered, for muscle conditioning
Product Code:	NGX
Device Class:	2
III. PREDICATE DEVICES	
510(k) Number:	K151903
Manufacturer:	Bio-Medical Research Ltd.
Trade Name:	SLENDERTONE® Connect Abs, Type 570

The listed predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The SLENDERTONE® Connect Abs, Type 570 is a portable, neuromuscular, electrical stimulation system intended to deliver electrical stimulation to the abdominal muscles. The system includes a control unit, abdominal garment, 3 adhesive gel pads (electrodes), USB cable, pouch and instructions for use. One toning program is pre-installed in the unit. Wireless communication is enabled by a Bluegiga BLE113 Bluetooth module. The modified Slendertone Connect Abs device supports a range of mobile devices via both iOS and android mobile applications.

V. INDICATIONS FOR USE

The SLENDERTONE® Connect Abs, Type 570 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is indicated for the improvement of abdominal muscle tone, for the strengthening of the abdominal muscles and for the development of a firmer abdomen.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following tables summarizes the similarities and differences between the technological characteristics of the modified device versus the predicate device;

Table I	Unit Characteristics
Table II	Output Characteristics (values representing maximum power limit of 180mW)

Users may securely download additional treatment programs through the mobile application. The program parameters and resulting outputs for any such program are limited in accordance with the Table II.

Table I **Basic Unit Characteristics**	**Modified Device** **Slendertone Connect Abs**	**Predicate Device** **Slendertone Connect Abs**	**Justification**
1. 510(k) Number	K161974	K151903	N/A
2. Device Name, Model	Slendertone® Connect Abs, Type 570	Slendertone® Connect Abs, Type 570	Same
3. Manufacturer (Contract)	JDI Electronics Factory Cima Industrial Center Chang Ping, Dongguan Guangdong, CHINA Owner Operator: Blue Ocean Innovation Ltd RM 1813, Fo Tan Industrial Centre 26-28 Au Pui Wan Street Fo Tan, Hong Kong	Blue Ocean Innovation Ltd RM 1813, Fo Tan Industrial Centre 26-28 Au Pui Wan Street Fo Tan, Hong Kong	
4. Power Source	3.7V Lithium Polymer Single Cell Rechargeable	3.7V Lithium Polymer Single Cell Rechargeable	Same
- Method of line Isolation	No line connection possible when connected to body	No line connection possible when connected to body	Same
- Patient Leakage Current	Not applicable, no line connection, no AC charger connection or operation. Connection method does not allow AC charger connection to Patient.	Not applicable, no line connection, no AC charger connection or operation. Connection method does not allow AC charger connection to Patient.	Same
5. No. of Output Modes	1 (Symmetric, Pulsed, Biphasic)	1 (Symmetric, Pulsed, Biphasic)	Same
6. Number of Output Channels	2	2	Same
- Synchronous/Alternating?	Synchronous	Synchronous	Same
- Method of channel isolation	Transistor	Transistor	Same
7. Regulated Current or Regulated Voltage	Constant Current	Constant Current	Same
8. Software/Firmware/Micro processor Control?	Yes	Yes	Same
9. Mobile Apps	iOS + Android	iOS only	Different, but does not adversely impact the safety and effectiveness of the subject device
10. Automatic overload Trip?	Yes	Yes	Same
11. Automatic No-Load	Yes	Yes	Same

Table I **Basic Unit Characteristics**	**Modified Device** **Slendertone Connect Abs**	**Predicate Device** **Slendertone Connect Abs**	**Justification**
Trip?			
12. Automatic Shut Off	Yes	Yes	Same
13. Patient Override Control?	Yes, pause button stops treatment immediately.	Yes, pause button stops treatment immediately.	Same
14. Indicator Display - On/Off Status? - Low Battery? - Voltage/Current Level?	 Yes, Unit LED and Smart device Yes, Unit LED and Smart device Yes, via Smart device	 Yes, Unit LED and Smart device Yes, Unit LED and Smart device Yes, via Smart device	Same
15. Timer range (minutes)	20-30 minutes	20-30 minutes	Same
16. Compliance with Voluntary Standards?	IEC 60601-1: 2005 & A1:2012 IEC 60601-2-10:2012 EN 60601-1-2: 2007 IEC 60601-1-11:2010 IEC 60601-1-6:2010 IEC 62133:2012 FCC Rule Part 15.247:2012	IEC 60601-1: 2005 & A1:2012 IEC 60601-2-10:2012 EN 60601-1-2: 2007 IEC 60601-1-11:2010 IEC 60601-1-6:2010 IEC 62133:2012 FCC Rule Part 15.247:2012	
17. Compliance with CFR 21 898?	Yes	Yes	Same
18. Weight (unit)	37g (including batteries)	37g (including batteries)	Same
19. Dimensions (un.) {W x H x D}	70 x 50 x 14 mm approx.	70 x 50 x 14 mm approx.	Same
20. Housing Materials and Construction	Injection molded thermosetting plastic	Injection molded thermosetting plastic	Same

Table II Output Characteristics	Modified Device Slendertone Connect Abs	Predicate Device Slendertone Connect Abs	Justification
Waveform	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic	Same
Shape	Rectangular, with interphase interval	Rectangular, with interphase interval	Same
Maximum Output Voltage (RMSV) (+/-10%) $-\sqrt{\frac{Vp^2 x 2 x PW}{1/freq}}$	9.47V @ 500Ω 17.5V @ 2kΩ 6.2V @ 10kΩ	9.47V @ 500Ω 17.5V @ 2kΩ 6.2V @ 10kΩ	Same
Maximum Output Current (RMSA) (+/-10%)	18.9mA @ 500Ω 8.75mA @ 2kΩ 620µA @ 10kΩ	18.9mA @ 500Ω 8.75mA @ 2kΩ 620µA @ 10kΩ	Same
Pulse Width	900 µS	900 µS	Same
Baseline to peak current @500Ω	80mA	80mA	Same
Frequency (Hz)	10 to 80 Hz	10 to 80 Hz	Same
- Phase Duration	100 - 400µS	100 - 400µS	Same
Net Charge (µC per pulse)	0@500Ω Symmetric, biphasic and leading polarity alternates for each successive pulse	0@500Ω Symmetric, biphasic and leading polarity alternates for each successive pulse	Same
Maximum Phase Charge (µC) C= Ip*PW	1 phase 32 µC @500Ω 2 phase 64 µC @500Ω	1 phase 32 µC @500Ω 2 phase 64 µC @500Ω	Same
Maximum Current Density (mA/cm^2)	0.28 mA/cm^2 @500Ω	0.28 mA/cm^2 @500Ω	Same
Maximum Power Density (W/ cm^2) Using smallest electrode conductive surface area	2.57 mW/ cm^2 @500Ω	2.57 mW/ cm^2 @500Ω	Same
Contraction Time	0.5 – 5 sec	0.5 – 5 sec	Same
Relaxation Time	0.5 – 6 sec	0.5 – 6 sec	Same
Additional Features (if applicable)	N/A	N/A	Same

VII. PERFORMANCE DATA

Performance testing was conducted in accordance with the following international standards for safety:

IEC 60601-1: 2005/A1:2012 Medical electrical equipment. General requirements for basic safety and essential performance

IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-2:2007	Medical electrical equipment - part 1-2: general requirements for safety -collateral standard: electromagnetic compatibility - requirements and tests
IEC 60601-2-10:2012	Medical Electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
IEC 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
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. Tests for irritation and skin sensitization

The performance of SLENDERTONE® Connect Abs for wireless co-existence was evaluated in an environment with equipment operating in the ISM band i.e. Bluetooth and Wi-Fi devices, cellphones, cordless phones etc.. The device met all specified requirements.

BLE module testing was conducted in accordance with EN 60950-1:2006+A11:2009 +A1:2010+A12:2011+A2:2013. Safety of Technology Equipment and FCC Rule Part 15.247:2012.

Battery testing was conducted in accordance with IEC 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them, for use in portable applications.

VIII. CONCLUSION

The modified SLENDERTONE® Connect Abs, Type 570 has

- The same principles of operation as the predicate device with no differences in technological characteristics.
- The same Intended Use and Indications for Use as the predicate device.

Modifications to the SLENDERTONE® Connect Abs has not resulted in any new issues of safety or effectiveness, and is therefore substantially equivalent to the predicate device.