DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 6, 2015

Bio-Medical Research Ltd.
Attn: Ms. Anne-Marie Keenan
Regulatory Affairs Specialist
Parkmore Business Park West,
Galway, IRELAND

Re: K151903
Trade 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 6, 2015
Received: October 9, 2015

Dear Ms. 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 27f 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 -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)*
K151903

Device Name
SLENDERTONE connect Abs, Type 570

Indications for Use *(Describe)*
The SLENDERTONE connect Abs 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.

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Bio-Medical Research Ltd.
Parkmore Business Park West, Galway, Ireland

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

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Prepared:	October 6, 2015

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:	K100320
Manufacturer:	Bio-Medical Research Ltd.
Trade Name:	Slendertone System Ultra, Type 390, Model E70/X70

510(k) Number:	K143551
Manufacturer:	DJO LLC.
Trade Name:	Compex Wireless USA

These predicates have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The *SLENDERTONE® Connect Abs*, Type 570 is a portable neuromuscular electrical stimulator intended to deliver electrical stimulation to the abdominal muscles. The device includes a control unit, abdominal garment, 3 adhesive gel pads (electrodes), USB cable and instructions for use. It contains one pre-installed program called 'Essential Toning'.

The *SLENDERTONE® Connect Abs* incorporates a Bluegiga BLE113 Bluetooth module to enable wireless communication and can be paired with a Bluetooth enabled iOS smart device running a Slendertone Connect iOS App, available from the Apple App store. The App implements a virtual control panel on the screen of the smart device where on-screen buttons are provided to the user.

The control unit is connected to the abdominal belt garment via an 8-pin interface. The control unit contains the primary controls for operation of the device and push buttons are available for switching the unit on or off and to increase or decrease the stimulation intensity. These controls remain active while the control unit is wirelessly paired with a smart device and can be used in the event of loss of Bluetooth connection. The *SLENDERTONE® connect Abs* contains light emitting diodes (LED) which indicate status relating to battery charge, stimulation and bluetooth activity. Power is derived from a 3.7V Li-Po rechargeable battery pack and the unit can be recharged by using the supplied USB cable.

The SLENDERTONE® Connect Abs, Type 570 is rated as IP22 for ingress protection. The user has no access to the wiring or connectors within the garment. For purposes of hygiene, the garment may be cleaned and instructions for garment care are included in the user manual.

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. The *SLENDERTONE® connect Abs*, Type 570 is intended for over-the-counter use.

The Indications for Use statement for the SLENDERTONE® connect Abs, Type 570 is not identical to the predicate devices; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicates.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

Table I	Unit Characteristics of new vs. predicate devices, Slendertone System Ultra and Compex Wireless USA
Table II	Output Characteristics of new vs. predicate device Compex Wireless USA (new device values representing maximum power limit of 180mW)

In future, users may securely download additional treatment programs through the mobile app. The program parameters and resulting outputs for any such program are limited in accordance with the Table II.

Table I **Basic Unit Characteristics**	**New Device** **Slendertone Connect Abs**	**Predicate Device** **Slendertone System Ultra**	**Predicate Device -** **Compex Wireless USA**
1. 510(k) Number	To be assigned	K100320	K143551
2. Device Name, Model	Slendertone Connect Abs, Type 570	Slendertone System Ultra Type 390, E70/X70	Compex Wireless USA
3. Manufacturer (Contract)	Blue Ocean Innovation Ltd RM 1813, Fo Tan Industrial Centre 26-28 Au Pui Wan Street Fo Tan, Hong Kong	China Turnkey Solutions Logistics (Shenzhen) Co., Futian Free Trade Zone CHINA 518038	DJO LLC
4. Power Source	3.7V Lithium Polymer Single Cell Rechargeable	3.6V NiMh Battery Pack Rechargeable	3.7V Lithium Polymer Single Cell.
- Method of line Isolation	No line connection possible when connected to body	No line connection possible when connected to body	No line connection possible when connected to body
- 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.	Not applicable, no line connection, no AC charger connection or operation. Connection method does not allow AC charger connection to Patient.
5. No. of Output Modes	1 (Symmetric, Pulsed, Biphasic)	1 (Symmetric, Pulsed, Biphasic)	1 (Symmetric, Pulsed, Biphasic)
6. Number of Output Channels	2	2	2
- Synchronous/Alternating?	Synchronous	Synchronous	Synchronous
- Method of channel isolation	Transistor	Transistor	Transistor
7. Regulated Current or Regulated Voltage	Constant Current	Constant Current	Constant Current
8. Software/Firmware/Microprocessor Control?	Yes	Yes	Yes, with Wireless control
9. Automatic overload Trip?	Yes	Yes	Yes
10. Automatic No-Load Trip?	Yes	Yes	Yes
11. Automatic Shut Off	Yes	Yes	Yes
12. Patient Override Control?	Yes, pause button stops treatment immediately.	Yes, pause button stops treatment immediately.	Yes, pause button stops treatment immediately.
13. Indicator Display - On/Off Status?	Yes, Unit LED and Smart device	Yes, LCD	Yes, LCD

Table I **Basic Unit Characteristics**	**New Device** **Slendertone Connect Abs**	**Predicate Device** **Slendertone System Ultra**	**Predicate Device -** **Compex Wireless USA**
- Low Battery? - Voltage/Current Level?	Yes, Unit LED and Smart device Yes, via Smart device	Yes, LCD Yes, LCD	Yes, LCD Yes, LCD
14. Timer range (minutes)	20-30 minutes	20-40 minutes	20-40 minutes
15. 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 60601-1:1988 & A1:1991, A2:1995 IEC 60601-2-10:1987 & A1 2001 IEC 60601-1-2:2001 (EN 60601-1-2:2001) CISPR 22:2003/CFR 47 Part 15:2005 IEC 60601-1-6:2004 (EN 60601-1-6:2001) Battery Charger: IEC 60950 and UL 1950 CC Rules Subpart B	
16. Compliance with CFR 21 898?	Yes	Yes	Yes
17. Weight (unit)	37g (inc batteries)	116g (inc. batteries)	2x60g
18. Dimensions (un.) {W x H x D}	70 x 50 x 14 mm approx.	60 x 23 x 115mm approx.	65 x 20mm
19. Housing Materials and Construction	Injection moulded thermosetting plastic	Injection moulded thermosetting plastic	plastic

Table II **Output Characteristics**	**New Device** **Slendertone Connect Abs**	**Predicate Device** **Compex Wireless USA**
Waveform	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic
Shape	Rectangular, with interphase interval	Rectangular, with interphase interval
Maximum Output Voltage (RMSV) (+/- 10%) $-\sqrt{\frac{Vp^2 x 2 x PW}{1/freq}}$	9.47V @ 500Ω 17.5V @ 2kΩ 6.2V @ 10kΩ	15.5V@500Ω 62.0V@2kΩ unknown
Maximum Output Current (RMSA) (+/- 10%)	18.9mA @ 500Ω 8.75mA @ 2kΩ 620µA @ 10kΩ	31mA@ 500Ω (estimated) 31mA@ 2kΩ (estimated) unknown
Pulse Width	900 µS	900µS
Baseline to peak current @500Ω	80mA	120mA
Frequency (Hz)	10 to 80 Hz	1 to 120 Hz
- Phase Duration	100 - 400µS	300 to 400 µS
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
Maximum Phase Charge (µC) C= Ip*PW	1 phase 32 µC @500Ω 2 phase 64 µC @500Ω	1 phase 48 µC @500Ω 2 phase 96 µC @500Ω
Maximum Current Density (mA/cm^2)	0.28 mA/cm^2 @500Ω	1.49 mA/cm^2 @500Ω Electrode 50mm square
Maximum Power Density (W/ cm^2) Using smallest electrode conductive surface area	2.57 mW/ cm^2 @500Ω	27.6 mW/ cm^2 @500Ω
Contraction Time	0.5 – 5 sec	4.5 – 11.0 sec

Table II **Output Characteristics**	**New Device** **Slendertone Connect Abs**	**Predicate Device** **Compex Wireless USA**
Relaxation Time	0.5 – 6 sec	4.5 – 31 secs
Additional Features (if applicable)	N/A	N/A

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

In addition, 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 *SLENDERTONE® connect Abs*, Type 570 has the same principles of operation as it's predicate devices and any differences in technological characteristics do not raise new issues of safety or effectiveness.
- The Indications for Use statement is not identical to the predicate devices; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device.
- Performance data has demonstrated that the *SLENDERTONE® Connect Abs, Type 570* is as safe and effective as the predicate devices and is substantially equivalent.