February 10, 2021

Bio-Medical Research Ltd.
Eoin Keating
Official Correspondent
Parkmore Business Park West
Galway, H91 NHT7
Ireland

Re: K203513
Trade/Device Name: SLENDERTONE Evolve Abs, Type 735
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: November 25, 2020
Received: November 30, 2020

Dear Eoin Keating:

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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203513

Device Name
SLENDERTONE® Evolve Abs, Type 735

Indications for Use *(Describe)*
The SLENDERTONE® Evolve Abs, Type 735 is indicated for the improvement of abdominal muscle tone, for strengthening of 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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Bio-Medical Research Limited,
Parkmore Business Park West, Galway, Ireland.
Tel: +353 (0)91 774300 Fax: +353 (0)91 774301

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

I. SUBMITTER

Name:	Mike Kilkelly
Address:	Bio-Medical Research Ltd., Parkmore Business Park West, Galway, IRELAND
Telephone:	+353 91 774395
Fax:	+353 91 774301 or +353 91 774302
E-Mail:	mkilkelly@bmr.ie
Prepared:	November 25, 2020

II. DEVICE

Trade Name of Device:	SLENDERTONE® Evolve Abs, Type 735
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:	K180688
Manufacturer:	Bio-Medical Research Limited.
Trade Name:	SLENDERTONE® Corefit Abs8, Type 734

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

IV. DEVICE DESCRIPTION

The SLENDERTONE® Evolve Abs, Type 735 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 twelve pre-installed programs.

The control unit is connected to the abdominal belt garment via three magnetic connectors. 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. The SLENDERTONE® Evolve Abs, Type 735 contains an Organic Light-Emitting Diode (OLED) display which indicates status relating to battery charge and stimulation. 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® Evolve Abs, Type 735 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® Evolve Abs, Type 735 is indicated for the improvement of abdominal muscle tone, for strengthening of abdominal muscles, and for the development of a firmer abdomen.

The Indications for Use statement for the SLENDERTONE® Evolve Abs, Type 735 is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table summarizes the similarities and differences between the technological characteristics of the new device and predicate device SLENDERTONE® Corefit Abs8, Type 734.

10.2 Output Specifications

The following information has been compiled using the "Guidance Document on Powered Muscle Stimulator 510(k)s, 1999".

Table I **Basic Unit Characteristics**	**New Device** SLENDERTONE® Evolve Abs, Type 735	**Predicate Device** SLENDERTONE® CoreFit Abs 8, Type 734	**Comparison**
1. 510(k) Number	(To be Assigned)	K180688	N/A
2. Device Name, Model	SLENDERTONE® Evolve Abs, Type 735	SLENDERTONE® CoreFit Abs 8, Type 734	N/A
3. Manufacturer (Contract)	China Turnkey Solutions Logistics (Shenzhen) Co., Futian Free Trade Zone CHINA 518038	China Turnkey Solutions Logistics (Shenzhen) Co., Futian Free Trade Zone CHINA 518038	Identical
4. Power Source	3.7V Lithium Polymer Single Cell Rechargeable	3.7V Lithium Polymer Single Cell Rechargeable	Identical
- Method of line Isolation	No line connection possible when connected to body	No line connection possible when connected to body	Identical
- 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.	Identical
5. No. of Output Modes	1 (Symmetric, Pulsed, Biphasic)	1 (Symmetric, Pulsed, Biphasic)	Identical
6. Number of Output Channels	2	2	Identical
- Synchronous/Alternating?	Synchronous	Synchronous	Identical
- Method of channel isolation	Transistor	Transistor	Identical
7. Regulated Current or Regulated Voltage	Constant Current	Constant Current	Identical
8. Software/Firmware/Microprocessor Control?	Yes	Yes	Identical

10.2 Output Specifications

The following information has been compiled using the "Guidance Document on Powered Muscle Stimulator 510(k)s, 1999".

Table I **Basic Unit Characteristics**	**New Device** SLENDERTONE® Evolve Abs, Type 735	**Predicate Device** SLENDERTONE® CoreFit Abs 8, Type 734	**Comparison**
9. Automatic overload Trip?	Yes	Yes	Identical
10. Automatic No-Load Trip?	Yes	Yes	Identical
11. Automatic Shut Off	Yes	Yes	Identical
12. Patient Override Control?	Yes, pause button stops treatment immediately.	Yes, pause button stops treatment immediately.	Identical
13. Indicator Display - On/Off Status? - Low Battery? - Voltage/Current Level?	 Yes, OLED Display Yes, OLED Display Yes, OLED Display	 Yes, OLED Display Yes, OLED Display Yes, OLED Display	Identical
14. Timer range (minutes)	2 - 45 minutes	20-40 minutes	Different but no impact on safety or effectiveness.
15. Compliance with Voluntary Standards?	IEC 60601-1 IEC 60601-2-10 EN 60601-1-2 IEC 60601-1-11 IEC 60601-1-6 IEC 62133 FCC (47 CFR Part 15, Subpart B)	IEC 60601-1 IEC 60601-2-10 EN 60601-1-2 IEC 60601-1-11 IEC 60601-1-6 IEC 62133 FCC (47 CFR Part 15, Subpart B)	Identical
16. Compliance with CFR 21 898?	Yes	Yes	Identical
17. Weight (unit)	37g (incl. batteries)	37g (incl. batteries)	Identical
18. Dimensions (un.) {W x H x D}	57 x 57 x 15 mm approx.	57 x 57 x 15 mm approx.	Identical

10.2 Output Specifications

The following information has been compiled using the "Guidance Document on Powered Muscle Stimulator 510(k)s, 1999".

Table I **Basic Unit Characteristics**	**New Device** SLENDERTONE® Evolve Abs, Type 735	**Predicate Device** SLENDERTONE® CoreFit Abs 8, Type 734	**Comparison**
19. Housing Materials and Construction	Injection moulded thermosetting plastic, with a thermoplastic elastomer (TPE) keypad	Injection moulded thermosetting plastic, with a thermoplastic elastomer (TPE) keypad	Identical

10.2 Output Specifications

The following information has been compiled using the "Guidance Document on Powered Muscle Stimulator 510(k)s, 1999".

Tabel II **Output Characteristics**	**New Device** SLENDERTONE® Evolve Abs, Type 735	**Predicate Device** SLENDERTONE® CoreFit Abs 8, Type 734	**Comparison**
Waveform	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic	Identical
Shape	Rectangular, with interphase interval	Rectangular, with interphase interval	Identical
Maximum Output Voltage (RMSV) (+/-10%) $\sqrt{\frac{Vp^2 x 2 x PW}{1/freq}}$	8.36V @ 500Ω 15.56V @ 2kΩ @ 10kΩ: no output for 10kΩ resistance	7.58V @ 500Ω 14.4V @ 2kΩ @ 10kΩ: no output for 10kΩ resistance	Different but no impact on safety or effectiveness. *See note below re Maximum output current
Maximum Output Current (RMSA) (+/-10%)	16.72mA @ 500Ω 7.78mA @ 2kΩ @ 10kΩ: no output for 10kΩ resistance	15.16mA @ 500Ω 7.2mA @ 2kΩ @ 10kΩ: no output for 10kΩ resistance	Different but no impact on safety or effectiveness *The values are well below safety limits of Table 201.101 "Pulse frequency versus applied current limits" of IEC 60601-2-10.
Pulse Width	800 µs	730 µs	Different but no impact on safety or effectiveness.
Baseline to peak current @500Ω	72mA	72mA	Identical
Frequency (Hz)	50-75 Hz	50-70 Hz	Identical
For interferential modes: - Beat Frequency	N/A	N/A	Identical

10.2 Output Specifications

The following information has been compiled using the "Guidance Document on Powered Muscle Stimulator 510(k)s, 1999".

Tabel II **Output Characteristics**	**New Device** SLENDERTONE® Evolve Abs, Type 735	**Predicate Device** SLENDERTONE® CoreFit Abs 8, Type 734	**Comparison**
For multiphasic waveforms only: - Symmetrical phases	Yes	Yes	Identical
- Phase Duration	200 - 350µs	200 - 315µs	Different but no impact on safety or effectiveness.
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	Identical
Maximum Phase Charge (µC) C= Ip*PW	1 phase 25.2 µC @500Ω	1 phase 22.8 µC @500Ω 2 phase 45.6 µC @500Ω	Different but no impact on safety or effectiveness.
Maximum Current Density (mA/cm^2)	0.279 mA/cm^2 @500Ω	0.216 mA/cm^2 @500Ω	Different but no impact on safety or effectiveness The values are well below the 2mA/cm2 value stated in Clause 201.7.9.2.101 item (g) of IEC 60601-2-10.
Maximum Power Density (W/ cm2) Using smallest electrode conductive surface area	2.33 mW/ cm^2 @500Ω	1.64 mW/ cm^2 @500Ω	Different but no impact on safety or effectiveness. The value is well below the maximum power density of 0.25 Watts/cm2 to reduce risk of thermal burns. ** **FDA Guidance document Reference FDA Guidance Document for Powered Muscle Stimulator 510(k)s.

10.2 Output Specifications

The following information has been compiled using the "Guidance Document on Powered Muscle Stimulator 510(k)s, 1999".

Tabel II **Output Characteristics**	**New Device** SLENDERTONE® Evolve Abs, Type 735	**Predicate Device** SLENDERTONE® CoreFit Abs 8, Type 734	**Comparison**
Contraction Time	1.0 – 60.0 s	1.0 – 5.5 s	Different but no impact on safety or effectiveness.
Relaxation Time	1.0 – 10.0 s	1.0 – 7.0 s	Different but no impact on safety or effectiveness.
Burst Mode	N/A	N/A	Identical
Additional Features (if applicable)	N/A	N/A	Identical
Maximum Charge Current	300mA @ 5V	300mA @ 5V	Identical

VII. PERFORMANCE DATA

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

IEC 60601-1	Medical electrical equipment. General requirements for basic safety and essential performance
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-2	Medical electrical equipment - part 1-2: general requirements for safety -collateral standard: electromagnetic compatibility - requirements and tests
IEC 60601-2-10	Medical Electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
IEC 60601-1-11	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

Battery testing was conducted in accordance with IEC 62133 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® Evolve, Type 735 has the same principles of operation as it's predicate device and any differences in technological characteristics do not raise new issues of safety or effectiveness.
- The Indications for Use statement is identical to the predicate device.
- Performance data has demonstrated that the SLENDERTONE® Evolve Abs, Type 735 is as safe and effective as the predicate device and is substantially equivalent.