October 25, 2018

Bio-Medical Research Ltd
Eoin Keating
Quality Engineer
Parkmore Business Park West
Galway, H91 NHT7 Ireland

Re: K180688
Trade/Device Name: SLENDERTONE CoreFit Abs 8, Type 734
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: September 12, 2018
Received: September 24, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 J. Pinto -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180688

Device Name
SLENDERTONE® CoreFit Abs 8, Type 734

Indications for Use *(Describe)*
The SLENDERTONE® CoreFit Abs 8, Type 734 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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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:	September 21, 2018

II. DEVICE

Trade Name of Device:	SLENDERTONE® CoreFit Abs 8, Type 734
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 (Primary Predicate)
Manufacturer:	Bio-Medical Research Ltd.
Trade Name:	Slendertone System Ultra, Type 390, Model E70/X70

IV. DEVICE DESCRIPTION

The SLENDERTONE® CoreFit Abs 8, Type 734 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 ten 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® CoreFit Abs 8, Type 734 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® CoreFit Abs 8, Type 734 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® CoreFit Abs 8, Type 734 is indicated for the improvement of abdominal muscle tone, for strengthening of abdominal muscles, and for the development of a firmer abdomen. SLENDERTONE® CoreFit Abs 8, Type 734 is intended for over-the-counter use.

The Indications for Use statement for the SLENDERTONE® CoreFit Abs 8, Type 734 is identical to the predicate device

VI. BIOCOMPATIBILITY EVALUATION

The SLENDERTONE® CoreFit Abs 8, Type 734 uses the same adhesive gel pads (electrodes) as the predicate device Slendertone System Ultra.

Biocompatibility testing of the SLENDERTONE® CoreFit Abs 8, Type 734 garment assembly was carried out. The four test studies conducted were as follows;

1. Cytotoxicity Test: MTT Method MEM with 10% FBS Extract
2. Cytotoxicity Test: MTT Method MEM Extract
3. Skin sensitization: Buehler test in guinea pigs
4. Skin irritation Test: Direct contact.

A summary of the four biocompatibility tests carried out can be seen in the below table.

Test	Result	Toxicological Conclusion
Cytotoxicity Test: MTT Method MEM with 10% FBS Extract	Potential toxicity at extract concentration >=75%	No toxicological risk to users.
Cytotoxicity Test: MTT Method MEM Extract	No potential cytotoxic potential	No toxicological risk to users.
Skin sensitization: Buehler test in guinea pigs	Dermal scoring using the Magnusson and Kligman scoring system was graded as 0 (no visible change)	No toxicological risk to users.
Skin irritation Test: Direct contact	No abnormal signs were observed during the study. The response of skin on test side did not exceed that on the control side.	No toxicological risk to users.

VII. 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 primary predicate device Slendertone System Ultra.

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Table I **Basic Unit Characteristics**	**New Device** SLENDERTONE® CoreFit Abs 8, Type 734	**Predicate Device** Slendertone System Ultra, Type 390, Model E70/X70
1. 510(k) Number	(To be Assigned)	K100320
2. Device Name, Model	SLENDERTONE® CoreFit Abs 8, Type 734	Slendertone System Ultra Type 390, E70/X70
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
4. Power Source	3.7V Lithium Polymer Single Cell Rechargeable	3.6V NiMh Battery Pack Rechargeable
- Method of line Isolation	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.
5. No. of Output Modes	1 (Symmetric, Pulsed, Biphasic)	1 (Symmetric, Pulsed, Biphasic)
6. Number of Output Channels	2	2
- Synchronous/Alternating?	Synchronous	Synchronous
- Method of channel isolation	Transistor	Transistor
7. Regulated Current or Regulated Voltage	Constant Current	Constant Current
8. Software/Firmware/Microprocessor Control?	Yes	Yes
9. Automatic overload Trip?	Yes	Yes
10. Automatic No-Load Trip?	Yes	Yes
11. Automatic Shut Off	Yes	Yes
12. Patient Override Control?	Yes, pause button stops treatment immediately.	Yes, pause button stops treatment immediately.
13. Indicator Display - On/Off Status?	Yes, OLED Display	Yes, LCD

Table I **Basic Unit Characteristics**	**New Device** SLENDERTONE® CoreFit Abs 8, Type 734	**Predicate Device** Slendertone System Ultra, Type 390, Model E70/X70
- Low Battery? - Voltage/Current Level?	Yes, OLED Display Yes, OLED Display	Yes, LCD Yes, LCD
14. Timer range (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 (47 CFR Part 15, Subpart B)	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 FCC Rules Subpart B
16. Compliance with CFR 21 898?	Yes	Yes
17. Weight (unit)	37g (incl. batteries)	116g (inc. batteries)
18. Dimensions (un.) {W x H x D}	57 x 57 x 15 mm approx.	60 x 23 x 115mm approx.
19. Housing Materials and Construction	Injection moulded thermosetting plastic, with a thermoplastic elastomer (TPE) keypad	Injection moulded thermosetting plastic

Table II **Output Characteristics**	**New Device** SLENDERTONE® CoreFit Abs 8, Type 734	**Predicate Device** Slendertone System Ultra, Type 390, Model E70/X70
Waveform	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic
Shape	Rectangular, with interphase interval	Rectangular, with interphase interval
Maximum Output Voltage (RMSV) (+/- 10%) $\sqrt{\frac{Vp^2 x 2 x PW}{1/freq}}$	7.58V @ 500Ω 14.4V @ 2kΩ @ 10kΩ: no output for 10kΩ resistance	7.4V@500Ω 15.4V@2kΩ 6.2V@10kΩ
Maximum Output Current (RMSA) (+/- 10%)	15.16mA @ 500Ω 7.2mA @ 2kΩ @ 10kΩ: no output for 10kΩ resistance	14.7mA@500Ω 7.7mA@2kΩ 620µA@10kΩ
Pulse Width	730 µs	730 µs
Baseline to peak current @500Ω	72mA	70mA
Frequency (Hz)	50-70 Hz	50-70 Hz
For interferential modes: - Beat Frequency	N/A	N/A
For multiphasic waveforms only: - Symmetrical phases	Yes	Yes
- Phase Duration	200 - 315µs	200/225/250/275/300/315 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 22.8 µC @500Ω 2 phase 45.6 µC @500Ω	1 phase 22 µC @500Ω 2 phase 44 µC @500Ω
Maximum Current Density (mA/cm^2)	0.216 mA/cm^2 @500Ω	0.21 mA/cm^2 @500Ω

Table II **Output Characteristics**	**New Device** SLENDERTONE® CoreFit Abs 8, Type 734	**Predicate Device** Slendertone System Ultra, Type 390, Model E70/X70
Maximum Power Density (W/ cm^2) *Using smallest electrode conductive surface area*	1.64 mW/ cm^2 @500Ω	1.59 mW/ cm^2 @500Ω
Contraction Time	1.0 – 5.5 s	1.0 - 5.5 s
Relaxation Time	1.0 – 7.0 s	1.0 – 7.0 s
Burst Mode	N/A	N/A
Additional Features (if applicable)	N/A	N/A
Maximum Charge Current	300mA @ 5V	400 mA @ 6V

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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/A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 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 60601-1-11:2015	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

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® CoreFit Abs 8, Type 734 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® CoreFit Abs 8, Type 734 is as safe and effective as the predicate device and is substantially equivalent.