AUG 02

K100554

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

1. Contact Details

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Prepared:	25th May 2010

2. Device Name

Trade Name of Device:	Flex Max by Slendertone, Type 517-US
Common Name:	Muscle Stimulator
Classification Name:	Stimulator, muscle, powered, for muscle conditioning
Regulation Number:	21 CFR 890.5850
Product Code:	NGX

3. Identification of Equivalent Legally Marketed Device

Name:	Slendertone Flex, Type 515
Manufacturer:	Bio-Medical Research Ltd.
510(k) No:	K030708, June 2003

4. Description of Device

Flex Max by Slendertone, Type 517-US is a two-channel battery operated muscle stimulation system specifically designed to exercise the abdominal muscles. It offers 10 programs to the user and comprises of two main components, an electronic stimulator module which generates the required stimulation signals and an abdominal electrode belt, which connects the signals from the stimulator to the skin electrodes located on the inner surface of the belt.

The product is supplied with a double set of double-sided adhesive electrodes, a double set of batteries, an extender belt and an instruction manual. Power is derived from 3 x 1.5 volt (LR03) batteries located in a compartment protected by a removable battery cover. Instructions are provided in the user instructions.

For purposes of hygiene, the garment may be cleaned and instructions for device care are included in the user manual.

5. Statement of Intended Use & Indications for Use

The Flex Max by Slendertone device has the same intended use and indications for use as the listed equivalent legally marketed device. It is intended for use by healthy persons to apply transcutaneous neuromuscular electrical stimulation ("NMES") through skin contact electrodes for the purpose of improving abdominal muscle tone, strength and firmness.

6. Technological Characteristics

The Flex Max by Slendertone device is identical to the predicate device in design, materials, mode of operation, and methods of manufacture. It differs only in the addition of different program offerings to the user.

7. Clinical and Non-Clinical Tests

The same technological platform and modus operandi is same as the predicate device, Slendertone Flex, Type 515. No additional clinical studies were provided as part of this submission. The Flex Max by Slendertone complies with international standards for electrical safety and electromagnetic compatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bio-Medical Research, Ltd.
% Ms. Deirdre Barrow
BMR House, Parkmore Business Park West
Galway, Ireland

AUG 02 2010

Re: K100556
Trade Name: Flex Max by Slendertone, Type 517-US
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: May 25, 2010
Received: June 4, 2010

Dear Ms. Barrow:

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.

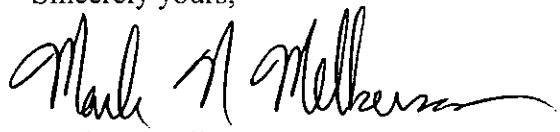
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

AUG 02 2010

Indications for Use

510(k) Number (if known): K100556

Device Name: Flex Max by Slendertone, Type 517-US

Indications for Use:

Flex Max by Slendertone is indicated for the improvement of abdominal muscle tone, for strengthening of the abdominal muscles and for the development of a firmer abdomen.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K100556