Bio-Medical Research Ltd.

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K100320

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

MAY - 5 2010

1. Contact Details

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Prepared:	25th January 2010

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2. Device Name

Trade Name of Device:	System Ultra, Type 390, Model E70/X70
Common Name:	Muscle Stimulator
Classification Name:	Stimulator, muscle, powered, for muscle conditioning
Product Code:	NGX

3. Identification of Equivalent Legally Marketed Device

Device Trade Name:	Slendertone System-Abs, Type 390 E10/X10 device
Manufacturer:	Bio-Medical Research Ltd
510(k) Nos:	K070142

4. Description of Device

System Ultra, Type 390, Model E70/X70 is a two-channel, battery powered, muscle stimulation system. It is supplied with a three-electrode abdominal belt garment, a hand-held rechargeable control unit, a pack of 3 adhesive backed gel based electrodes, instructions for use and a carry pouch.

The control unit is interchangeable between all the cleared System models from the Slendertone® range of garments reference Table 10.1

Table 10.1 System from Slendertone Range of devices

Device	Type, Model No.	510k No.
System-Abs (Female Version)	Type 390, E10	K070142
System-Abs (Male Version)	Type 390, X10	K070142
System-Shorts	Type 390, E20	K070142
System-Mini	Type 390, E30	K072294
System-Arms	Type 390, E60	K072553
System-Arms	Type 390, X60	K083164

There are ten programs available to users of the System Ultra, Type 390, E70/X70. Power is derived from a 3.6V NiMH rechargeable battery pack pre-installed in the unit.

All the internal connections are over-molded to prevent moisture ingress. The user has no access to the wiring or connectors within the garment and is unable to alter the current path.

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

5. Statement of Intended Use/Indications for Use

The proposed device, System Ultra, Type 390, E70/X70 is a powered muscle stimulator intended for over-the-counter use; there is no change to the indications for use from the predicate product Slendertone System-Abs, Type 390, E10/X10.

Proposed Device: "System Ultra, Type 390, Model E70/X70" is intended for the improvement of abdominal muscle tone, for the strengthening of the abdominal muscles and for the development of a firmer abdomen.

6. Technological Characteristics

The System Ultra, Type 390, E70/X70 incorporates the control unit and garment technology of the existing predicate Slendertone System-Abs, Type 390, E10/X10 (K070142).

7. Clinical and Non-Clinical Tests

No new clinical studies have been submitted as part of this premarket notification.

System Ultra, Type 390, E70/X70 device complies with the following international safety standards:

- IEC 60601-1:1988 & A1:1991, A2:1995 Medical electrical equipment - Part 1: General requirements for safety
- IEC 60601-2-10:1987 & A1 2001 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
- IEC 60601-1-2:2001 (EN 60601-1-2:2001) Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

The battery charger complies to safety standards IEC 60950 and UL 1950

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. Deidre Barrow
Quality/Regulatory Engineer
Parkmore Business Park, West
Galway, Ireland

MAY - 5 2010

Re: K100320
Trade/Device Name: Slendertone System Ultra, Type 390, Model E70/X70
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: January 26, 2010
Received: February 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

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Slendertone System Ultra, Type 390, Model E70/X70

Indications for Use:

The Slendertone System Ultra is indicated for the improvement of abdominal muscle tone, for the 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 K100320