K070142

**510(k) Summary**

MAR 2 3 2007

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

## 1. Contact Details


| | |
|---|---|
| Name: | Anne-Marie Keenan |
| Address: | Bio-Medical Research Ltd.,<br>Parkmore Business Park, West<br>Galway, Ireland |
| Telephone: | +353 91 774300 |
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| Prepared: | 13th March 2007. |


## 2. Device Name

| | |
|---|---|
| Trade Name of Device: | System-Abs, Type 390, E10/X10<br>System-Shorts, Type 390, E20 |
| Common Name: | Muscle Stimulator |
| Classification Name: | Stimulator, muscle, powered, for muscle conditioning (NGX) |

## 3. Identification of Equivalent Legally Marketed Device

System-Abs, Type 390, E10/X10

| | | |
|---|---|---|
| Name: | Slendertone Flex, Type 515 | Slendertone Flex, Type 512 |
| Manufacturer: | Bio-Medical Research Ltd. | Bio-Medical Research Ltd. |
| 510(k) No: | K030708, June 2003 | K010335, Sept. 2001 |

System-Shorts, Type 390, E20

| | |
|---|---|
| Name: | Slendertone Flex Bottom and Thigh Toning System, Type 511 |
| Manufacturer: | Bio-Medical Research Ltd. |
| 510(k) No: | K022855, March 2003 |

## 4. Description of Device

System-Abs and System-Shorts are the newest product offerings from Slendertone (division of Bio-Medical Research Ltd.). The products include an interchangeable, rechargeable handheld controller, which can be used with a garment from the System range, to exercise specific areas of the body. The System-Abs belt is used to exercise the abdominal muscles and the System-Shorts is used to exercise the bottom and thigh muscles.

The overall product consists of a garment (shorts for System-Shorts and belt for System-Abs), control unit, a pack of adhesive backed gel based electrodes (6 for System-Shorts and 3 for System-Abs), battery charger and instruction manual.

System is a two-channel EMS product and offers 7 programs to the user of the belt and 4 programs to users of the shorts. Electrodes are applied to the inner surface of the garment to cover the silver studs and the garment is fitted (sizing options are given for a best fit) using the hook and loop patches. Each System garment contains an ID chip, which is programmed to determine the different model types and treatment parameters and is connected to the electronic controller unit via a lead and connector. The control unit generates the required stimulation signals and the garment connects these signals to the skin electrodes. Power is derived from a 3.6V NiMH rechargeable battery pack that is pre-installed in the unit.

There is no current passed from side to side. Because the user has no access to the wiring or connectors within the garment, he/she cannot alter the current path and so the possibilities for misuse are greatly reduced.

The product cannot be used whilst in charge mode.

Materials:
(Belt): Outer -100% Nylon, Binding – 82% Nylon, 18% Elastane, Hook and Loop – 100% Nylon, Foam – 100% Polyurethane

(Shorts): Outer -100% Nylon, Binding – 82% Nylon, 18% Elastane, Hook and Loop – 100% Nylon, Non-Elastic Hook and Loop – 100% Polyethylene, Foam – 100% Polyurethane, Stitch String – 100% Nylon.

## 5. Statement of Intended Use/Indications for Use

Indications for use are the same as the listed predicate devices. System from Slendertone is intended for use by healthy persons to apply trans-cutaneous electrical muscle stimulation (EMS) through skin contact electrodes. Indications for used are as follows:

System-Abs, Type 390, E10/X10

- The improvement of abdominal muscle tone, for the strengthening of the abdominal muscles and for the development of a firmer abdomen.

System-Shorts, Type 390, E20

- Strengthening, toning and firming of the bottom and thigh region.

## 6. Summary of Technological Characteristics

A summary of the technological characteristics of the System devices compared to the predicate devices in terms of design, material, chemical composition and energy source is given below:

| | **Proposed Device**<br>**System-Abs, Type 390, E10/X10**<br><br>**System-Shorts, Type 390, E20** | **Predicate Devices**<br>**Flex, Type 515 (K030708), Slendertone Flex, Type 512 (K010335)**<br><br>**Flex Bottom and Thigh Toning System, Type 511 (K022855)** |
|---|---|---|
| **Design** | Handheld controller connected to the garment via a lead. Control unit is interchangeable between the System range of garments.<br><br>Rechargeable battery<br><br>ID chip contained in garment. | Unit is contained within holster on garment<br><br>Disposable AAA (LR03) batteries<br><br>Program parameters contained in controller memory. |
| **Material** | (Belt): Outer -100% Nylon, Binding – 82% Nylon, 18% Elastane, Hook and Loop – 100% Nylon, Foam – 100% Polyurethane<br><br>(Shorts): Outer -100% Nylon, Binding – 82% Nylon, 18% Elastane, Hook and Loop – 100% Nylon, Non-Elastic Hook and Loop – 100% Polyethylene, Foam – 100% Polyurethane, Stitch String – 100% Nylon. | Same |
| **Chemical Composition** | N/A | N/A |
| **Energy Source** | Rechargeable Battery (3.6V) | 3 x LR03 batteries (4.5V) |

## 7. Clinical and Non-Clinical Tests

Clinical Tests: No new clinical studies have been submitted as part of this Premarket Notification. Clinical information submitted as part of the original predicate submissions K010335 Flex, Type 512 and K022855 Flex Bottom and Thigh Toning System, Type 511 are applicable to this Premarket Notification.

Non-Clinical Tests: System has been designed and independently tested to the following requirements:

- EN 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2001).
- CISPR 22:2003 – Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement & CFR 47 Part 15:2005 – Radio Frequency Devices.
- DIN EN 60601-1:1996; EN 60601-1:1990+A1:1993+A2:1995 Medical electrical equipment - Part 1: General requirements for safety
- IEC 60601-1:1988, IEC 60601-1/A1:1991, IEC 60601-1/A2:1995
- DIN EN 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators, IEC 60601-2-10
- Battery Charger complies to safety standards IEC 60950 and UL 1950

## 8. Safety and Effectiveness

System has been designed and developed under design project D188 to minimize risks and to ensure efficacy. Bio-Medical Research Ltd. (Division Slendertone) is registered to IS EN ISO 13485:2003 for the design, manufacture and distribution of electro-medical devices.

A risk management plan was carried out to EN ISO 14971:2001.

Independent EMC and Electrical Safety testing has been carried out.

In Europe (EU), System has been CE marked and complies with the Medical Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 2007

BioMedical Research Ltd.
% Ms. Anne-Marie Keenan
Quality/Regulatory Engineer
Parkmore Business Park West
Galway, Ireland

Re: K070142
Trade/Device Name: System-Abs, Type 390, E10/X10
System-Shorts, Type 390, E20
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: January 9, 2007
Received: January 16, 2007

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.

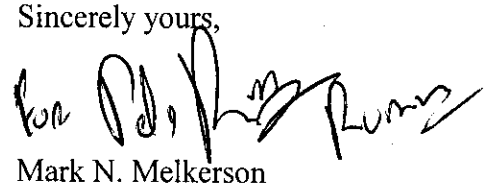
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

# Indications for Use

510(k) Number (if known): _____

Device Name: System-Abs, Type 390, E10/X10

Indications for Use:

The improvement of abdominal muscle tone, for the strengthening of the abdominal muscles and for the development of a firmer abdomen.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070142

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# Indications for Use

510(k) Number (if known): _____

Device Name: System-Shorts, Type 390, E20

Indications for Use:

System-Shorts Type 390, E20 is indicated for the strengthening, toning and firming of the bottom and thigh region.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)