K072294

Bio-Medical Research Ltd.

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510(k) Summary

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

1. Contact Details

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Prepared:	08th August 2007.

OCT 25 2007

2. Device Name

Trade Name of Device:	System-Mini, Type 390, Model E30
Common Name:	Muscle Stimulator
Classification Name:	Stimulator, muscle, powered, for muscle conditioning (NGX)

3. Identification of Equivalent Legally Marketed Device

Name:	System-Shorts, Type 390, E20
Manufacturer:	Bio-Medical Research Ltd
510(k) No:	K070142, March 2007

4. Description of Device

System-Mini, Type 390, Model E30 is a two-channel, battery powered muscle stimulation system. It consists of a skirt-shaped garment which is available in small (24-38"), medium (36-45") and large (40-48") sizes for best fit, a pack of 4 electrodes and instructions for use and is used with the Slendertone® System rechargeable handheld control unit which may be purchased separately or used from an existing Slendertone® System device i.e. System-Abs, Type 390, E10/X10 or the predicate System-Shorts, Type 390, Model E20.

The four equal sized electrodes (6 cm x 15 cm) are attached to the inner surface of the garment to cover stainless steel studs by using the electrode outlines to ensure correct placement. The garment is connected to the control unit by a lead and an over-molded SATA 7-pin connector, which incorporates an EEPROM (ID chip) device.

As with the predicate System-Shorts, the ID chip contains the data that identifies the garment type and the stimulation parameters intended for that garment. The model number of the garment itself is displayed on the LCD at power-on and on a label on the garment. When the control unit is connected to the garment, the data is read, identifying the specific garment type and also the stimulation parameters. The appropriate signals are then delivered to the

garment electrodes. There are four programs in total available to the System-Mini user and these are designated as "beginner", "intermediate", "advanced" and "expert". All 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.

Power is derived from a 3.6V NiMH rechargeable battery pack that is pre-installed in the unit. As with the predicate System-Shorts, System-Mini cannot be used when in charge mode.

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

System-Mini, Type 390, Model E30 is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation ("EMS") through skin contact electrodes for the purpose of exercising the gluteal muscles.

Proposed indications for use are: Strengthening, toning and firming of the bottom.

System-Mini, Type 390, Model E30 is intended for over-the-counter use.

6. Technological Characteristics

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

	Proposed Device	Predicate Device
Name	System-Mini	System-Shorts
Type	Type 390, E30	Type 390, E20
510k No.	Not Assigned	K070142
Design		
Garment	Skirt-shaped garment with ID Chip	Shorts-shaped garment with ID Chip
Control Unit	Slendertone-System Controller Handheld, Rechargeable	Same
Electrodes	4 in total Size 6 x 15 cm Axelgaard Manufacturing Co. 510k No. K000947	6 in total 9.5 x 5cm (4) and 10 x 10cm (2) Axelgaard Manufacturing Co. 510k No. K000947
Material	Outer Material: 80% Cotton, 10% Polyester, 5% Elastane, 5% Nylon; Inner Material: 80% Polyurethane, 5% Nylon, 5% Polychloroprene, 5% Polyester, 5% Elastane; Hook & Loop: 90% Nylon, 10% Elastane.	Outer Material-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.

Chemical Composition	N/A	N/A
Energy Source	Rechargeable Battery (3.6V) Charger: US/Japan Charger BMR p/n 2504-0302	Same

7. Clinical and Non-Clinical Tests

No new clinical studies have been submitted as part of this Premarket Notification.

Slendertone System has been 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. Conclusion

Bio-Medical Research Ltd., of which a subsidiary is Slendertone, is registered to IS EN ISO 13485:2003 for the design, manufacture and distribution of electro-medical devices. In the European Union and its associated territories, System-Mini is CE marked and complies with the Medical Device Directive 93/42/EEC.

Both the proposed System-Mini and predicate System-Shorts use identical electronic hardware. The principal physical difference is that the proposed System-Mini device omits two electrodes of the predicate device, which were located over the quadriceps. The electrical output into the body, as measured by the rms current is comparable. Likewise, the maximum current density at the electrodes is less than or equal to the predicate device. Therefore, no new safety issues arise with the proposed device.

The predicate device, System Shorts was shown to be effective for the improvement of strength, firmness and tone of the bottom and thigh muscles. The proposed device, System Mini, delivers effective gluteal component of the therapy.

In conclusion, it can be determined that the new device System-Mini, Type 390, Model E30 is substantially equivalent to System-Shorts, Type 390, Model E20. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 25 2007

Re: K072294
Trade Name: System-Mini, Model 390, E30
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: September 18, 2007
Received: September 25, 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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 Statement

510(k) Number (if known): _____

Device Name: System-Mini, Type 390, Model E30

Indications for Use:

System-Mini, Type 390, Model E30 is indicated for the strengthening, toning and firming of the bottom.

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 General, Restorative, and Neurological Devices

510(k) Number k072294