K072553

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

DEC 1 4 2007

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Prepared:	5th September 2007, Revised 5th December 2007

2. Device Name

Trade Name of Device:	System-Arms, Type 390, Model E60
Common Name:	Muscle Stimulator
Classification Name:	Stimulator, muscle, powered, for muscle conditioning (NGX)

3. Identification of Equivalent Legally Marketed Device

Name:	System-Abs, Type 390, Model E10 and X10
Manufacturer:	Bio-Medical Research Ltd
510(k) No:	K070142, March 2007

4. Description of Device

System-Arms, Type 390, Model E60 is a two-channel, battery powered muscle stimulation system. The System-Arms accessory pack consists of two arms garments (left and right arm), four straps, a pack of 4 adhesive backed gel based electrodes, instructions for use (manual and separate quick start guide) and a carry pouch. The hand-held control unit, which may be purchased separately, is interchangeable between all the System models from Slendertone® range of garments (i.e. System-Abs Type 390, Model E10/X10, System-Shorts Type 390, Model E20, System-Mini, Type 390, Model E30 and System Arms Type 390, Model E60).

The four equal sized electrodes (approx. size 50 x 50 mm) are attached to the inner surface of the garments to cover stainless steel studs by using the electrode outlines to ensure correct placement. The garments are connected to the control unit by leads and an over-molded SATA 7-pin connector, which also incorporates the EEPROM (ID chip) device.

As with the predicate System-Abs, 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 combination, the data is read, identifying the specific garment type and also the stimulation parameters. The appropriate signals are then delivered to the garment electrodes. Three programs in total (beginner, intermediate and advanced) are available to the System-Arms user. All internal connections are over-molded to prevent moisture ingress and the user has no access to the wiring or connectors within the garments 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-Abs, System-Arms cannot be used when charging.

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

System-Arms, Type 390, Model E60 is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation ("EMS") through skin contact electrodes for the purpose of exercising the muscles of the upper arms.

Indications for use: Toning of the triceps muscles of the upper arms.

System-Arms, Type 390, Model E60 is intended for over-the-counter use.

6. Technological Characteristics

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

	Proposed Device	Predicate Device
Name	System-Arms	System-Abs
Type	Type 390, E60	Type 390, E10/X10
510k No.	Not Assigned	K070142
Design		
Garment	2 arms garments with ID Chip	1 belt-shaped garment with ID Chip
Control Unit	System from Slendertone® Controller Handheld, Rechargeable	Same
Electrodes	4 in total Size: 50mm x 50mm Manufacturer: Axelgaard Manufacturing Co. 510k No. K000947	3 in total Size: 1 x center electrode approx. 100mm x 100mm, 2 x side electrodes approx. 70mm X 100mm Same
Material	2 x arms garments constructed of Outer Material - 80% Nylon, 20% Polyester, Inner Material - 100% Polyester laminated to 100% Polyurethane, Binding - 100% Nylon, Hook & Loop - 100% Nylon, Foam - EVA, Elasticated Straps - 100% Nylon	1 x abdominal garment constructed of Outer Material-100% Nylon, Binding – 82% Nylon, 18% Elastane, Hook and Loop – 100% Nylon, Foam – 100% Polyurethane
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

A single-blind, prospective, randomized, controlled trial "The effect of triceps brachii electrical muscle stimulation training on muscle strength, arm anthropometrics, triceps brachii

skinfold and psychometric measures" used to measure the efficacy of the Slendertone Arm toning product has been included as part of this submission.

System from Slendertone® has also 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 EEEA, System-Arms is CE marked and complies with the Medical Device Directive 93/42/EEC.

Both the proposed System-Arms and predicate System-Abs use identical electronic hardware. The principal physical difference, due to the difference in the targeted muscles, is the garment offering and the number, size and positioning of the electrodes.

The predicate device, System-Abs was shown to be effective for the improvement of strength, firmness and tone of the abdominal muscles. The proposed device, System-Arms delivers effective toning component of the therapy.

In conclusion, it can be determined that the new device System-Arms, Type 390, Model E60 is substantially equivalent to System-Abs, Type 390, Model E10/X10.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

Biomedical Research Ltd
% Anne-Marie Keenan
Parkmore Business Park West
Galway
Ireland

Re: K072553
Trade/Device Name: System-Arms Type 390, E60
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: November 12, 2007
Received: November 15, 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.

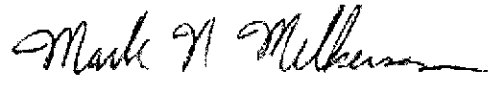
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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): K072553

Device Name: System-Arms, Type 390, Model E60

Indications for Use:

Toning of the triceps muscles of the upper arms.

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 K072553