DEC 1 6 2008

Bio-Medical Research Ltd.

Parkmore Business Park West, Galway, Ireland
Tel: +353 (0)91 774300 - Fax: +353 (0)91 774301

K083164

This 510(k) summary 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.,
	Parkmore Business Park, West
	Galway, Ireland
Telephone:	+353 91 774300
Fax:	+353 91 774301
E-Mail:	akeenan@bmr.ie
Prepared:	24th October 2008
Revised:	2nd December 2008

2. Device Name

Trade Name of Device:	System Arms, Type 390, Model X60
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:	EnerVive, Type 561	System-Arms Type 390, E60
Manufacturer:	Bio-Medical Research Ltd	Bio-Medical Research Ltd
510(k) Nos:	K071666	K072553

4. Description of Device

System Arms, Type 390, Model X60 is a two-channel, battery powered, muscle stimulation system. It is supplied with two arms garments (left & right arm), a hand-held rechargeable control unit, a pack of 4 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 (i.e. System-Abs Type 390, Model E10/X10, System-Shorts

Type 390, Model E20, System-Mini, Type 390, E30 and also System Arms Type 390, Model E60).

There are three programs available to users of the System Arms, Type 390, X60. 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

System Arms, Type 390, Model X60 is intended for use by healthy adults to apply Neuromuscular Electrical Simulation (NMES) via adhesive electrodes to healthy muscles of the upper arms in order to improve or facilitate the muscle performance of the triceps and biceps muscles.

Proposed indications for use: System Arms (Type 390, X60) is intended to stimulate healthy muscles in order to improve or facilitate muscle performance of the triceps and biceps muscles.

System Arms, Type 390, Model X60 is intended for over-the-counter use.

6. Technological Characteristics

The System Arms (Type 390, X60) incorporates the control unit and garment technology of the existing predicate System Arms (K072553).

7. Clinical and Non-Clinical Tests

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

The System Arms, Type 390, X60 device has been CE marked under the Medical Device Directive 93/42/EEC (NB No. 0366) and also 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
- CISPR 22:2003/CFR 47 Part 15:2005
- IEC 60601-1-6:2004 (EN 60601-1-6:2001) Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomedical Research Limited
% Ms. Anne-Marie Keenan
Parkmore Business Park, West
Galway
Ireland

DEC 16 2008

Re: K083164
Trade/Device Name: System Arms (Type 390, X60)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: December 2, 2008
Received: December 4, 2008

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 Biometrics' (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,

for Mark N. Melkerson Dep Dir 12/15/08

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 Arms (Type 390, X60)

Indications for Use:

System Arms (Type 390, X60) is intended to stimulate healthy muscles in order to improve or facilitate muscle performance of the triceps and biceps muscles.

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)

FOR M. MELKERSON

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

510(k) Number K083164