Bio-Medical Research Ltd.
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K091317

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

JUN 25 2009

## 1. Contact Details

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|---|---|
| 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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| E-Mail: | akeenan@bmr.ie |
| Prepared: | 30th April 2009. |

## 2. Device Name

| | |
|---|---|
| Trade Name of Device: | Lumbofix® Conductive Garment, Type 420 Back |
| Common Name: | Transcutaneous Electrical Nerve Stimulator for Pain Relief |
| Classification: | Class II |
| Product Code: | GZJ |

## 3. Identification of Equivalent Legally Marketed Device

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|---|---|
| Device Trade Name: | Baxolve XP Conductive Garment Accessory & Lumbar Support Kit |
| Manufacturer: | Bio-Medical Research Ltd |
| 510(k) No: | K082190 |

## 4. Description of Device

The Lumbofix® Conductive Garment is a conductive garment intended for use in conjunction with transcutaneous electrical nerve stimulation (TENS). It aids in the placement of electrodes and secures them in place. Contents include a conductive belt, a pack of hook backed electrodes and instructions for use.

## 5. Indications for Use

The Lumbofix® Conductive Garment provides symptomatic relief and management of chronic and intractable pain in the lower back region and assists in the frequent and correct positioning and repositioning of pads on difficult to reach and/or large locations of the lower back. It is intended for prescription use only.

## 6. Technological Characteristics

There are no new technological characteristics that could affect safety or effectiveness of the Lumbofix® Conductive Garment. Substantial Equivalence has been demonstrated as part this 510k submission.

## 7. Clinical and Non-Clinical Tests

Bio-Medical Research Ltd. ("BMR") has over 30 years experience in the research, design, manufacture and marketing of medical grade products for both muscle strengthening and pain relief. Bio-Medical Research Ltd. (Slendertone & Neurotech) complies with 21 CFR 820 and is registered to I.S. EN ISO 13485:2003 Medical Device Quality Management System for the design, manufacture and distribution of electro-medical devices.

No new clinical studies have been submitted as part of this premarket notification. The Lumbofix® Conductive Garment has been CE marked under the EU Medical Device Directive 93/42/EEC (NB No. 0366).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2009

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

Re: K091317
Trade Name: Lumbofix® Conductive Garment, Type 420 Back
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: April 30, 2009
Received: May 28, 2009

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kevia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number (if known): K091317

Device Name: Lumbofix® Conductive Garment

Indications for Use:

The Lumbofix® Conductive Garment:

- provides symptomatic relief and management of chronic and intractable pain in the lower back region and
- assists in the frequent and correct positioning and repositioning of pads on difficult to reach and/or large locations of the lower back.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

6/24/09

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091317