Bio-Medical Research Ltd.
Parkmore Business Park West, Galway, Ireland
Tel: +353 (0)91 774300 - Fax: +353 (0)91 774301

K082190

This summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

MAR 1 1 2009

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:	29th July 2008
Revised:	18th February 2009

2. Device Name

Name of Device:	Baxolve XP Conductive Garment Accessory & Lumbar Support Kit
Type Number:	297 & 298 (Lumbar Support only)
Proposed Regulatory Class:	Class II (Class I for Lumbar Support Device)

Regulation Description	Regulation Number	Product Codes
Transcutaneous Electrical Nerve Stimulator for Pain Relief	21 CFR 882.5890	GZJ
Truncal Orthosis	21 CFR 890.3490	IQE
Cutaneous Electrode	21 CFR 882.1320	GXY

3. Identification of Equivalent Legally Marketed Device

1. Name:	Neurotech Baxolve,
Manufacturer:	Bio-Medical Research Ltd
510(k) No:	K023913
2. Name	Ultrastim Kit
Manufacturer:	Axelgaard Mfg. Co. Ltd.
510(k) No:	K013532

4. Description of Device

The Baxolve XP Conductive Garment Accessory and Lumbar Support Kit (Types 297 and 298) is an innovative and comfortable to wear lumbar support belt. It is intended to help relieve lower back pain. The belt is supplied with a detachable sacral pad ("pelotte") that is covered with a stretch towel cover and can be attached to the inside of the belt. For additional comfort, this pelotte includes an array of flexible rubber fingers that ensure the compressive force and it can accommodate movement during walking. The belt may be used simply as a lumbar support device and can provide an adjustable degree of compression to the lumbo-sacral region due to the elasticated nature of the belt itself. To optimize support in the lumbar spine area, Baxolve XP incorporates "Duopress", an easy to adjust twin compression belt system. Compression may be increased with the optional detachable external compression straps.

The type 297 version of the Baxolve XP garment may be connected to transcutaneous Electrical Nerve Stimulation (TENS) devices manufactured by Bio-Medical Research Ltd. and is supplied with a pack of four adhesive pads, four electrode stud covers and instructions for use.

The type 298 Baxolve XP garment is similar to the type 297 garment except it is intended as a stand-alone lumbar support device.

For purposes of hygiene, the Baxolve XP garment may be cleaned and instructions for device care are included in the user manual.

5. Statement of Intended Use/Indications for Use

The Baxolve XP Conductive Garment Accessory and Lumbar Support Kit (type 297) can be used with a FDA cleared TENS device, manufactured by Bio-Medical Research Ltd., or alternatively on it's own as a stand-alone lumbar support device. A separate version (type 298) is also available for use as a stand-alone lumbar support device. These devices are for prescription use only.

Type 297

(a) Can be used on its own as a lumbar support device or as a conductive garment for use with cleared Transcutaneous Electrical Nerve Stimulation (TENS) devices for the following:

- The symptomatic relief and management of chronic and intractable pain in the lower back region.
- Assists in correctly positioning and repositioning pads on difficult to reach locations of the lower back
- Lumbar support

Type 298:

Can be used on its own as a lumbar support device only:

6. Technological Characteristics

There are no technological characteristics in the Baxolve XP Conductive Garment Accessory and Lumbar Support Kit that could affect either the safety or effectiveness of the devices.

7. Clinical and Non-Clinical Tests

Bio-Medical Research Ltd. complies with 21 CFR 820 Medical Device Quality System Regulations and also I.S. EN ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)

The Baxolve XP Conductive Garment Accessory and Lumbar Support Kit comply with EN ISO 14971:2007 Medical devices - Application of risk management to medical devices (ISO 14971:2007). Baxolve XP Conductive Garment Accessory and Lumbar Support Kit has also been CE marked under the Medical Device Directive 93/42/EEC. No clinical studies have been submitted as part of this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

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

Re: K082190
Trade/Device Names: Baxolve XP Conductive Garment Accessory & Lumbar Support Kit, Types 297 & 298
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ, IQE, GXY
Dated: February 18, 2009
Received: February 20, 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 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

510(k) Number (if known): _____

Device Name: Baxolve XP Conductive Garment Accessory & Lumbar Support Kit, Types 297 & 298

Indications for Use:

Type 297

Can be used on its own as a lumbar support device or as a conductive garment for use with cleared Transcutaneous Electrical Nerve Stimulation (TENS) devices for the following:

- The symptomatic relief and management of chronic and intractable pain in the lower back region.
- Assists in correctly positioning and repositioning pads on difficult to reach locations of the lower back
- Lumbar support

Type 298

Can be used on its own as a lumbar support device only:

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K082490