Bio-Medical Research Ltd.

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K092791

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

1. Contact Details

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Prepared:	3rd September 2009

DEC 30 2009

2. Device Name

Trade Name of Device:	Kneehab XP Controller (Type 411)
Common Name:	Muscle Stimulator
Classification Name:	Powered Muscle Stimulator
Regulation Number:	21 CFR 890.5850
Product Code:	IPF

3. Identification of Equivalent Legally Marketed Device

Name:	Kneehab XP Conductive Garment, Type 411
Manufacturer:	Bio-Medical Research Ltd.
510(k) No:	K083105

4. Description of Device

The Kneehab XP Controller is a portable, two-channel transcutaneous electrical muscle stimulator incorporating multipath®, a patented technology developed by neurotech®. It is designed to work in conjunction with the Kneehab XP Conductive Garment and electrodes to deliver highly focused and accurate quadriceps contractions by using constant current pulses to stimulate the nerves in the quadriceps area of the body.

The Kneehab XP controller is supplied with a rechargeable control unit, battery charger and instructions for use. Power is derived from a 3.6V NiMH rechargeable battery pack that is pre-installed in the unit. The controller may be only be connected to the garment/electrodes or the charger due to the utilisation of a single custom connector. All the internal connections of the unit are over-molded to prevent moisture ingress. There are three treatment programs in total with duration of 20 minutes each and details of these are included in the instructions for use.

5. Statement of Intended Use/Indications for Use

The Kneehab XP Controller applies muscle and nerve stimulation by using the principles of Neuromuscular Electrical Nerve Stimulation (NMES). NMES is the application of electrical stimulation of the peripheral nervous system to contract a muscle either through the direct activation of the motor neurons in the mixed peripheral nerve, or indirectly through reflex recruitment.

The Kneehab XP Controller is indicated for muscle re-education of the quadriceps, maintaining or increasing range of motion of the knee joint, prevention or retardation of disuse atrophy in the quadriceps, early post-surgical quadriceps strengthening and improved post-surgical knee stability secondary to quadriceps strengthening and increasing local blood circulation.

6. Technological Characteristics

There are no new technological characteristics that could affect safety or effectiveness of the Kneehab XP Controller, Type 411 device. The Kneehab XP Controller is substantially equivalent to the predicate device Kneehab XP Conductive Garment cleared under K083105.

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. BMR has two divisions – Slendertone, which develops and markets a range of consumer health and fitness products and Neurotech, which provides a range of neuromuscular stimulators for pain management and rehabilitation. Bio-Medical Research Ltd. 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.

The Kneehab XP Controller, Type 411 unit complies with the following electrical safety and EMC international standards:

- IEC 60601-1 (1998) + A1: 1991, A2: 1995, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2 (2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility Requirements & Tests.
- IEC 60601-2-10 (1987) + A1: 2001 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Bio-Medical Research Ltd.,
% Ms. Anne-Marie Keenan
Parkmore Business Park, West
Galway, Ireland

Re: K092791
Trade/Device Name: Kneehab XP Controller, Type 411
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: November 25, 2009
Received: December 2, 2009

DEC 30 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Kneehab XP Controller, Type 411

Indications for Use:

- Muscle re-education of the quadriceps,
- Maintaining or increase range of motion of the knee joint,
- Prevention or retardation of disuse atrophy in the quadriceps,
- Early post-surgical quadriceps strengthening and improved post-surgical knee stability secondary to quadriceps strengthening,
- Increasing local blood circulation.

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)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092791