# Bio-Medical Research Ltd.

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K082011

**510(k) Summary**

NOV 2 8 2008

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

## Contact Details:


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|---|---|
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| Prepared: | 11th July 2008 |


## Device Information:

| | |
|---|---|
| Trade Name: | Meditens XP, Type 458 (Device 1) |
| Common Name: | Muscle Stimulator |
| Classification Name: | Stimulator, Nerve, Transcutaneous, For Pain Relief |
| Regulation Number: | 21 CFR 882.5890 |
| Product Code: | GZJ |
| Equivalent Device: | Meditens Plus, Type 290 |
| Manufacturer: | Bio-Medical Research Ltd |
| 510(k) No: | K014020, July 2002 |

| | |
|---|---|
| Trade Name: | Medistim XP, Type 281 (Device 2) |
| Common Name: | Muscle Stimulator |
| Classification Name: | Stimulator, Muscle, Powered |
| | Stimulator, Nerve, Transcutaneous, For Pain Relief |
| Regulation Number: | 21 CFR 890.5850, 21 CFR 882.5890 |
| Product Code: | IPF, GZJ |
| Equivalent Device: | Medistim Plus, Type 291 |
| Manufacturer: | Bio-Medical Research Ltd |
| 510(k) No: | K014019, July 2002 |

## Description Of Devices:

Meditens XP and Medistim XP are portable two-channel battery operated stimulators. They consist of a Meditens XP or Medistim XP unit, instructions for use, 9-volt battery, two connecting lead-wires for connecting the stimulator unit to the electrodes, adhesive electrodes and a device box. The units for Meditens XP and Medistim XP are identical and can be identified by the use of different bezels. The software for each device is pre-configured during manufacturing and may not be accessed by either the user or clinician. Meditens XP offers a total of five treatment programs and Medistim XP offers nine treatment programs. Safety features are incorporated into the device to reduce the possibility of misuse.

## Intended Use/Indications for Use:

Both Meditens XP and Medistim XP are intended for prescription use only.

Meditens XP delivers stimulation based on the principles of transcutaneous electrical nerve stimulation (TENS). It is indicated for the symptomatic relief and management of chronic intractable pain. It is also an adjunctive treatment in the management of post-surgical and post-traumatic pain. The device has no curative value and should only be used in conjunction with medical supervision.

Medistim XP delivers stimulation based on the principles of Neuromuscular Electrical Nerve Stimulation (NMES) and also Transcutaneous Electrical Nerve Stimulation (TENS). The indications for use are as follows: Neuromuscular Electrical Stimulation for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and maintaining or increasing range of motion. Transcutaneous Electrical Nerve Stimulation (TENS) for an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

## Technological Characteristics:

There are no new technological characteristics that could affect safety or effectiveness of the Meditens XP or Medistim XP devices. The new devices have the same technological features as the predicate devices.

## 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. 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 clinical studies have been submitted as part of this premarket notification.

Meditens XP and Medistim XP comply with the following international safety standards:

- EN 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and Tests.
- EN 60601-1 (1990) + A1 (1993) + A2 (1995) +A13 (1996) + Corrigenda (July 1994) – Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC 60601-2-10, 1st ed., 1987 - Medical Electrical Equipment Part 2: Particular Requirements For The Safety Of Nerve And Muscle Stimulators.

A risk management plan has been carried out to I.S. EN ISO 14971 2001 AMD 1 2003.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

NOV 2 8 2008

Re: K082011
Trade/Device Name: MediStim XP, Type 281 and MediTens XP, Type 458
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ, IPF
Dated: October 9, 2008
Received: October 21, 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,

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: MediTens XP, Type 458

Indications for Use:

The symptomatic relief and management of chronic intractable pain. It is also an adjunctive treatment in the management of post-surgical and post-traumatic pain. The device has no curative value and should only be used in conjunction with medical supervision.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Runa M

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

Dep Dir + Acting Dir 11/28/08

**510(k) Number** K082011

# Indications for Use

510(k) Number (if known): _____

Device Name: MediStim XP, Type 281

Indications for Use:

- Neuromuscular Electrical Stimulation (NMES) for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and maintaining or increasing range of motion.

- Transcutaneous Electrical Nerve Stimulation (TENS) for an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

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)