JUL 11 2002

K014019

510(k) Summary of safety and effectiveness.

This summary is submitted in accordance with 21 CFR 807.92

a) Submitted by	Bio-Medical Research Ltd BMR House Parkmore Business Park, West Galway Republic of Ireland.
Contact person	Michelle Sawyer
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Title	Regulatory Affairs Specialist.
Date of preparation	04 December 2001.
Trade name of Device	NT MediStim PLUS
Common name	Powered muscle stimulator
Classification name	External functional neuromuscular stimulator
Identification of predicate Device.	Staodyn EMS +2

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Description of the device.

The MediStim PLUS is a portable two-channel battery operated neuromuscular electrical stimulator. The device is intended for prescriptive use per 21 CFR 801.109. It comprises of the device and two colour differentiated lead wires, which connect to four skin surface electrodes.
The device is powered by a 9-volt (type 6F22) battery located in a compartment to the rear of the device with a detachable battery cover.
The device is supplied with a set of adhesive electrodes, a carrying case, the user instruction manual and a battery.
Built in safety features are clearly outlined in this submission, which greatly reduce the possibility of mis-use.

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Intended use.

The MediStim PLUS is intended for use with a wide range of patients, some of who may have limited dexterity. It is intended to use the principles of neuromuscular electrical nerve stimulation through skin contact surface electrodes for the purpose of activation of weak and atrophied muscles or the inhibition of overactive muscle.

Technological comparison.

The MediStim PLUS is similar to the EMS+2 in that it delivers a stimulation signal. which is almost identical with similar parameter settings. The MediStim PLUS has an LCD screen with user compliance monitoring, where as the EMS+2 does not have this feature.

Non-clinical tests.

The MediStim PLUS was designed to. and has been independently tested to IEC 601-1: 1998 +A1: 1991+ A2: 1995, IEC 601-2-10:1987. IEC 601-1-2:1993.
Bio-Medical Research LTD adheres to recognised and established industry practices and all devices are subject to final performance testing.
A Hazard analysis, risk analysis and failure mode effects analysis have been carried out for the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2002

Mrs. Michelle Sawyer
Bio-Medical Research Ltd.
BMR House
Parkmore Business Park West
Galway, Ireland

Re: K014019
Trade/Device Name: Neurotech Medstim PLUS, Type 291
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: April 10, 2002
Received: April 15, 2002

Dear Mrs. Sawyer:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
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):	**Not available** K014019
Device Name:	**NeuroTech MediStim PLUS, Type 291.**
Sponsor Name:	**Bio-Medical Research Ltd. (NeuroTech is a division of Bio-Medical Research Ltd.)**

Indications for use.

The MediStim PLUS is indicated 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**
- **Maintaining or increasing range of motion.**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ☒

Over –The –Counter- Use ☐

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

510(k) Number K014019