K023916

APR 1 5 2004

Bio-Medical Research Ltd
Parkmore Business Park, West
Galway
Ireland

510 (k) Summary of Safety and Effectiveness.

This summary is submitted in accordance with 21 CFR 807.92

a)	1	Submitted by	Bio-Medical Research Ltd BMR House Parkmore Business Park, West Galway Republic of Ireland
		Establishment Registration Number	8020867
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		Title	Regulatory Affairs Manager
		Date of Preparation	November 2002.
	2	Trade Name of Device	NeuroTech© BackTENS & Lumbar support Type 294.
		Common Name	NeuroTech© BackTENS & Lumbar support.
		Classification name	Transcutaneous Electrical Nerve Stimulator.(882.5810)
	3	Identification of predicate device	NeuroTech© Smart-TENS , Type 456, Clearance ref# K961376.

4 Description of Device

The NeuroTech BackTENS device is a self-contained battery operated transcutaneous electrical muscle stimulator. The adhesive electrodes are mounted on a belt offering lumbar support to the user during therapy delivery.

The device is intended to provide a non-invasive therapy for over the counter sale.

5 Intended Use

The device is indicated for:

- Transcutaneous Electrical Nerve Stimulation (TENS), which provides the symptomatic relief and management of chronic lower back pain.
- Lumbar support.

6 Technological Comparison

The NeuroTech BackTENS is similar to the Smart-TENS in it's delivery of the stimulation signal and has similar parameter settings. Both products utilise a LCD screen with user compliance logging.

7 Non- clinical Tests

Comparisons of electrical outputs for the two devices show similar results. They have both been designed and independently tested to the following requirements;

- IEC 60601-1:1990 Medical electrical equipment – Part 1: General requirements for safety.
- IEC 60601-2-10
- IEC 601-1-1 and appendices A1:1991,A2:1995
  IEC 601-1-2: EMC requirements
- IEC 61000-4-2:1995: Electromagnetic compatibility
- IEC 61000-4-3:1997: Electromagnetic compatibility
- DD ENV 50204:1996: Electromagnetic compatibility
- EN 55011:1998: radiated emissions.

Bio-Medical Research Ltd, (BMR), adheres to recognised and established industry practice, and all devices are subject to final performance testing.

A hazard analysis, a risk analysis and a 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

APR 1 5 2004

Carol O'Donnell, Ph.D.
Clinical and Regulatory Affairs Manager
Bio-Medical Research Limited
BMR House
Parkmore Business Park
West Galway
Ireland

Re: K023916
Trade Name: NeuroTech© Back TENS and Lumbar Support, Type 294
Regulation Number: 21 CFR 882.5890, 21 CFR 882.1320, and 21 CFR 890.3490
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief, Cutaneous electrode, and Truncal orthosis
Regulatory Class: II
Product Code: GZJ, GXY, and IQE
Dated: January 8, 2004
Received: January 16, 2004

Dear Dr. O'Donnell:

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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. 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,

for Mark N. Melkerson

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

510(k) Number (if known):K023916

Device Name: neurotech BACKTENS & Lumbar Support Device, type 294

Indications For Use:

The neurotech BACKTENS device is intended to provide temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal daily activities

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K023916