K024258

510(k) Summary

MAR 4 - 2005

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
		Contact Person	Anne-Marie Keenan
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		Title	Quality/Regulatory Engineer
		Date of Preparation	December 2002
		Date of Update	February 2005
	2	Trade Name of Device	NeuroTech© Kneehab™
		Common Name	Muscle Stimulator
		Classification name	External functional neuromuscular stimulator. (822.5810)
	3	Identification of predicate device	Stoadyn EMS +2
	4	Description of Device	

The NeuroTech© Kneehab™ is a battery operated, portable neuromuscular electrical stimulator. The device is intended to provide a non-invasive, prescriptive therapy.

In use, the device delivers brief electrical pulses through the skin contact adhesive electrodes. It uses constant current pulses to stimulate the nerves in the quadriceps area of the body. These pulses cause muscular contraction through the application of stimulation to the peripheral nervous system.

The NeuroTech© Kneehab™ is a garment based solution comprising of a two-piece construction, which is wrapped around the patient's quadriceps above the knee. It is a one-programme unit.

5 Intended Use

The device is indicated for the following:

- 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.

6 Technological Comparison

There are many powered muscle stimulators with similar technological characteristics. We are not, however, aware of any powered muscle stimulator with identical indications to the NeuroTech© Kneehab™ product, i.e. specific for stimulation of the quadriceps muscles.

The following device has been chosen as the predicate as it is a general-purpose stimulator with indications, which include prevention and retardation of muscle atrophy and muscle re-education :

Staodyn EMS+2	K926510	Manufactured by Staodyn Inc, Longmount,Co.

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) of which NeuroTech© is a trading division, 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.

Section 2. Descriptive information.

2.1 Intended use.

The NeuroTech© Kneehab™ is a battery operated, portable neuromuscular electrical stimulator. The device is intended to provide a non-invasive, prescriptive therapy.
The device is indicated for:

- 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.

The device is more fully described in section 4.

In use, the device delivers brief electrical pulses through the skin contact adhesive electrodes. It uses constant current pulses to stimulate the nerves in the quadriceps area of the body. These pulses cause muscular contraction through the application of stimulation to the peripheral nervous system.

The NeuroTech© Kneehab™ is a garment based solution comprising of a two-piece construction, which is wrapped around the patient's quadriceps above the knee. It is a one-programme unit.

The device is for prescriptive use.

2.2 System components.

- Kneehab™ control unit.
- Kneehab™ under garment.
- 3 x 1.5 V type LR03 (AAA) batteries.
- Adhesive electrode pads (Type; 613 x 1/614 x 1/615 x 1/616 x 2)
- User instruction manual.
- Cardboard insert for storage.

A more detailed description is provided in section 4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 - 2005

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

Re: K024258
Trade/Device Name: NeuroTech® Kneehab™ Type 410
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: II
Product Code: IPF
Dated: February 24, 2005
Received: February 28, 2005

Dear Mrs. Anne-Marie 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.

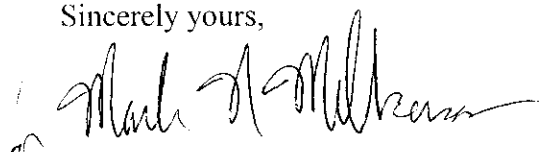
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120 . 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 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/industry/support/index.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): K024258

Device Name: NeuroTech® Kneehab™ Type 410.

Sponsor Name: Bio-Medical Research Ltd.

The device is intended for prescriptive use.

Indications for Use:

- 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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ☒

Over –The –Counter- Use ☐

for Mark N. Milhauser

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

510(k) Number K024258