SEP 1 1 2002

K022776
10P2

ATTACHMENT 7-1.

510(K) SUMMARY

N.E.S.S. NEUROMUSCULAR ELECTRICAL STIMULATION SYSTEMS LTD.

NESS SYSTEM

POWERED MUSCLE STIMULATOR

Applicant: N.E.S.S. Neuromuscular Electrical Stimulation Systems Ltd.
19 Ha-Haroshet Street
Keidar Center
Suite 207
P.O. Box 2500
Industrial Zone
Ra'anana, 43465
ISRAEL
Tel: 011-972-9-7485738
Fax: 011-972-9-7485740

Contact Persons:

Orly Maor
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 011-972-9- 7718130
Fax: 011- 972-9-7718131

And/or

Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109
Tel: (202) 637-5794
Fax: (202) 637-5910

Trade Name: NESS System

Common/Usual Name: External Neuromuscular Stimulator

Classification Name: Powered Muscle Stimulator

K022776
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Predicate Device:

N.E.S.S. Neuromuscular Electrical Stimulation Systems Handmaster NMS1 (K952273, and K982482).

Intended Use:

The NESS System is intended to be used for the following indications: maintenance or increase of range of motion, reduction of muscle spasm, prevention or retardation of disuse atrophy, muscle reeducation, and increasing local blood circulation.

Device Description:

The NESS System is a portable, one-channel electrical neuromuscular stimulator for personal use. The stimulator, which is powered by rechargeable nickel-cadmium batteries, serves surface electrodes held on to the limb by a splint. A selection of four splints for the hand and forearm, the arm, the thigh, or the leg is provided.

A single channel of constant-voltage symmetrical biphasic Russian waveform stimulation is delivered to the muscles through surface electrodes. Microprocessor-controlled switching of the stimulation between these electrodes allows the muscles to be activated in combinations either cyclically or continuously. The stimulation is ramped up at the beginning and down at the end of each cycle.

The electrode locations allow the NESS System to provide extension and flexion of the limb segment distal to that of the splint. The user can select from five stimulation programs by pressing the mode button on the control unit and can increase or decrease the stimulation intensity in ten discrete levels.

Predicate Device & Substantial Equivalence

The NESS System is substantially equivalent to the market-cleared Handmaster NMS1. The only difference between the NESS System and the Handmaster NMS1 is the provision of additional plastic splints to allow the system to treat other sites on the limbs: the upper arm, the thigh, and the lower leg.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2002

Neuromuscular Electrical Stimulation Systems, Ltd.
C/O Jonathan S. Kahan
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K022776
Trade/Device Name: NESS System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPG
Dated: August 21, 2002
Received: August 21, 2002

Dear Mr. Kahan:

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) 594-4659. 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,

for Mark N Milhran

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

ATTACHMENT 7-3.

INDICATIONS FOR USE STATEMENT

510(k) Number:_____

Device Name:

NESS System

Indications for Use:

The NESS System is intended to be used for the following indications:

- maintenance or increase of range of motion,
- reduction of muscle spasm,
- prevention or retardation of disuse atrophy,
- muscle reeducation, and
- increasing local blood circulation.

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

510(k) Number _____

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

for Mark N Milham
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022776