

SEP 30 1998

K 982/82

**510(K) SUMMARY**

**N.E.S.S. NEUROMUSCULAR ELECTRICAL STIMULATION  
SYSTEMS LTD.'S MODIFIED HANDMASTER NMS1 POWERED  
MUSCLE STIMULATOR**

**Submitter's Name, Address, Telephone Number, Contact Person  
and Date Prepared**

**Submitter:** 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

**Phone:** 011-972-7485738  
**Facsimile:** 011-972-7485740

**Contact Persons:** Giora Arbel  
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

**Phone:** 011-972-7485738  
**Facsimile:** 011-972-7485740

Jonathan S. Kahan, Esq.  
Hogan & Hartson, L.L.P.  
555 Thirteenth Street, N.W.  
Washington, D.C. 20004-1109

**Phone:** 202-637-5794  
**Facsimile:** 202-637-5910

Date Prepared: July 16, 1998

**Name of Device and Name/Address of Sponsor**

The HANDMASTER NMS1

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

Phone: 011-972-7485738  
Facsimile: 011-972-7485740

**Common or Usual Name**

External Neuromuscular Stimulator

**Classification Name**

Powered Muscle Stimulator

**Predicate Devices**

N.E.S.S. Neuromuscular Electrical Stimulation Systems HANDMASTER  
NMS1 (K952273).

**Intended Use**

The HANDMASTER NMS1 is intended to be used to exercise the lower arm and hand by activating the muscles thereof with electrical stimulation. As a powered muscle stimulator, the HANDMASTER NMS1 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.

### **Technological Characteristics and Substantial Equivalence**

The HANDMASTER NMS1 is a portable, one-channel electrical neuromuscular stimulator for personal use in exercising the upper extremity. The stimulator serves five surface electrodes held on to the upper limb by a splint. The control unit housing the stimulator may be worn using the shoulder strap provided, or it may be placed on any stable surface. The splint is worn on the hand and forearm. The splint is connected to the control unit by a light cable.

The HANDMASTER NMS1 is used for exercising the hand, conditioning selected muscles of the forearm and hand. It is intended for use by patients suffering from upper limb paralysis due to injury or disease of the central nervous system such as cervical spinal cord injuries or stroke.

A single channel of constant-voltage symmetrical biphasic Russian waveform stimulation is delivered to the muscles through five surface electrodes. Microprocessor-controlled switching of the stimulation between these five 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 HANDMASTER NMS1 to give finger and thumb extension and flexion. The user can select from five stimulation programs by pressing the mode button on the control unit. The active mode is displayed by a light glowing next to the labeled mode. When the device is

stimulating, the light flashes. The stimulation programs are supplied as microprocessor firmware. They comprise either cyclic or continuous activation of the finger and thumb extensors and flexors.

The user can increase or decrease the stimulation intensity in ten discrete levels by pressing on buttons labeled "+" or "-" on the control unit. This alters the duration of the stimulation pulse. The intensity is displayed as a number (0 to 9) on a seven-segment display.

During the initial system set-up, the clinician opens a clinical panel within the control unit. Adjustments are provided for limiting the maximum current to the extensor muscles and to the flexor muscles, along with a global timing factor which increases or decreases the duration of the stimulation cycles, effectively speeding or slowing the cyclic hand motion.

The user starts or stops the stimulation program by pressing a "trigger" button. If required, the user may also stop all stimulation immediately by switching OFF the device.

The HANDMASTER NMS1 splint is used to hold the wrist joint at a comfortable extension angle (20°), and also to hold the electrodes on the forearm and hand segments. It is constructed from fiber-reinforced plastic with soft polyurethane cushion sections to distribute stress over bony regions. The electrodes are made from metal foil coated with carbon-impregnated polymer. Replaceable water-soaked cloth pads are arranged over the electrodes to provide a

conductive interface with the skin. A sponge-capped bottle is provided to facilitate wetting of the electrode pads.

Rechargeable nickel-cadmium batteries power the device. Battery status can be displayed both during device operation and while recharging the batteries. Both visual and audio battery-low warnings are provided. It is necessary to disconnect splint/electrodes in order to recharge the batteries, as the same socket is used for both.

The modified HANDMASTER NMS1 is substantially equivalent to the original HANDMASTER NMS1, a marketed powered muscle stimulator. The modified HANDMASTER NMS1 and its predicate device have the same intended use, which is to exercise the limb by activating the muscles with electrical stimulation. Like the modified HANDMASTER NMS1, the predicate device is capable of delivering electrical stimulation to surface electrodes positioned on the skin surface of the limb. In addition, both the modified HANDMASTER NMS1 and the predicate device are operated either in flexion/extension cyclic mode or in a continuous mode.

The modification to the original HANDMASTER NMS1 will not alter the cleared device's intended use or indications for use. The sole change to be made is that the modified device would produce a higher frequency carrier wave than the original HANDMASTER NMS1. The currently cleared HANDMASTER NMS1 has a carrier wave frequency of 5,000 Hz, and the proposed modification would increase the carrier wave frequency to 11,000 Hz. No other changes will be made to the

amplitude or shape of the waveform, or any other technological characteristics. Importantly, the modification to the HANDMASTER NMS1 could not impact safety or effectiveness because it is well recognized in the medical literature that the stimulation frequency, not the carrier wave frequency, determines the effect and comfort of the stimulation. Hence, according to FDA's framework for substantial equivalence, the 11,000 Hz device is substantially equivalent to the 5,000 Hz device.

### **Performance Data**

Oscilloscope Tracing Specification tests have been carried out on the modified HANDMASTER NMS1 per Section 1 of the Draft FDA Guidance entitled "Technological Reporting for Powered Muscle Stimulators". This testing measured the stimulator output for the modified HANDMASTER NMS1 at various intensity levels, output loads and operating modes.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Neuromuscular Electrical Stimulation System (N.E.S.S.) Ltd.  
c/o Mr. Jonathan S. Kahan  
Partner  
Hogan & Hartson  
555 Thirteenth Street NW  
Columbia Square  
Washington, DC 20004-1109

Re: K982482  
Trade Name: Handmaster NMS1  
Regulatory Class: II  
Product Code: IPF  
Dated: July 16, 1998  
Received: July 16, 1998

Dear Mr. Kahan:

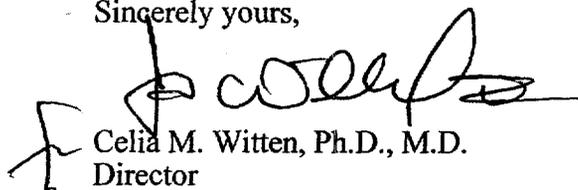
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

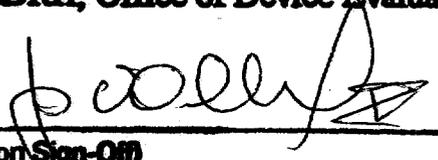
510(k) Number (if known): K982482

Device Name: HANDMASTER NMS1

Indications For Use: The HANDMASTER 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K982482

Prescription Use X  
(per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_