MAY 21 1998

510(k) Summary
Neotonus, Inc. MS-101 Magnetic Muscle Stimulator System

K973929

1. Sponsor

Neotonus, Inc.
810-A Franklin Court
Marietta, GA 30067

Contact Person: Tony J. Morris
President

Date Prepared: May 21, 1998

2. Device Name

Classification Name: Powered Muscle Stimulator, 21 CFR 890.5850, Product Code 89IPF, Class II
Proprietary Name: MS-101 Magnetic Muscle Stimulator System

3. Intended Use

The Neotonus MS-101 Magnetic Muscle Stimulator System is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

The Neotonus MS-101 is indicated for use in stimulating neuromuscular tissues for bulk muscle excitation in the legs or arms for rehabilitative purposes.

Indications for Use for Muscle Stimulators:

- 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

4. Device Description

The MS-101 Magnetic Muscle Stimulator System consists of a stimulator Control Unit and a Treatment Wand. The Control Unit is used to generate a voltage signal that

periodically charges a "C" shaped magnetic coil which is held against the patient's skin nearest the muscle group to be stimulated. Controls are available to vary the pulse frequency (1-55 Hz), pulse amplitude (0-100%), on-cycle "Duty" period (1-30 sec) and off-duty "Rest" period (0-60 sec).

5. Basis For Substantial Equivalence

The MS-101 is substantially equivalent to electrical stimulators used for muscle rehabilitation and the indications as stated above. In particular, the MS-101 is substantially equivalent to the RICH-MAR Theratouch electrical muscle stimulator. A clinical study was conducted to compare the physiological effect of the MS-101 to that of the RICH-MAR electrical stimulator. The knee extensor muscles of nine healthy volunteers with varying degrees of muscle tone were stimulated using both the MS-101 and the electrical muscle stimulator. The study showed that:

- The skeletal muscle responses evoked by the MS-101 were comparable to those evoked using the RICH-MAR electrical stimulator.
- Both types of stimulation evoked the classic sigmoidal relationships between stimulus amplitude and muscle torque and between stimulus frequency and muscle torque.
- Both types of stimulation evoked the classic muscle fatigue and increased one-half relaxation time with repeat contractions.
- The MS-101 is substantially equivalent to electromyostimulation for muscle rehabilitation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1998

Mr. James R. Veale
Vice President, Regulatory Services
Medical Device Consultants, Inc.
Representing Neotonus, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K973929
Neotonus MS-101 Magnetic Muscle Stimulator System
Regulatory Class: II
Product Code: IPF
Dated: February 18, 1998
Received: February 20, 1998

Dear Mr. Veale:

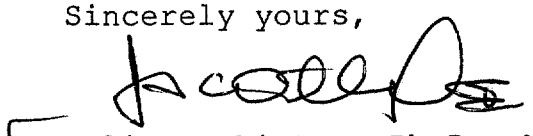
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Premarket 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): K973929

Device Name: NEOTONUS MS-101 MAGNETIC MUSCLE STIMULATOR SYSTEM

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Robert J. DeLuca

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973929