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510(k) Summary

Neotonus, Inc.
Model 1000 Muscle Stimulator System

1. Sponsor

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

Contact Person: Tony J. Morris
President

Date Prepared: May 28, 1998

2. Device Name

Proprietary Name:	NEOTONUS Model 1000 Muscle Stimulator System
Common/Usual Name:	Pelvic floor stimulator
Classification Name:	Nonimplanted electrical continence device

3. Intended Use

The NEOTONUS Model 1000 Muscle Stimulator System is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in women.

4. Device Description

The Model 1000 Muscle Stimulator System consists of a stimulator control unit and a treatment chair. The stimulator control unit is used to generate a voltage signal that periodically charges an "E" shaped magnetic coil located beneath the seat of the treatment chair. Controls are available to vary the pulse frequency (1-55 Hz), pulse amplitude (0-100%), on-cycle "Duty" period (1-30 sec) and off-cycle "Rest" period (0-60 sec).

During treatment, the patient sits on the treatment chair with the pelvic floor area centered over the magnetic coil. The magnetic field emitted by the coil induces an electric field in the target tissue that causes contraction of the pelvic floor musculature. The patient is treated fully clothed and there is no need for an invasive electrode probe. Treatment is suggested as up to 30 minutes per session, with sessions separated by at least 2 days.

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5. Basis For Substantial Equivalence

The Model 1000 Muscle Stimulator System is substantially equivalent to electrical stimulators used for the treatment of incontinence, including the InCare Pelvic Floor Therapy System (K961872), the Hollister Microgyn Plus Stimulation Device (K963222), the Utah Medical Liberty System (K960496), and the Minnova Pelvic Floor Stimulation System (K970307).

A clinical evaluation was conducted to compare the physiological effect of the Model 1000 to that of an electrical stimulator. Ten females received treatment with both the Model 1000 and an electrical stimulator. Treatment parameters were similar for both devices. Response was measured by evaluating the EMG activity of the urethral sphincter muscle and the pressure in the urethra during stimulation.

Urethral pressures were not affected by either magnetic or electrical stimulation. Muscle contractions in the urethral sphincter were visual and palpable for both types of stimulation. In all cases, the magnitude of the sphincter muscle activity produced by the magnetic stimulation was larger than that produced by the electrical stimulation. Most patients preferred the magnetic stimulation as more comfortable than the electrical stimulation. The results of this study support the substantial equivalence of the NEOTONUS Model 1000 Muscle Stimulator System to electrical stimulators for the treatment of urinary incontinence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 1998

Neotonus, Inc.
c/o Mr. James R. Veale
Vice President, Regulatory Services
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K973096
Neotonus Model 1000 Muscle Stimulator System
Dated: May 28, 1998
Received: May 29, 1998
Regulatory Class: II
21 CFR 876.5320/Procode: 78 KPI

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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973096

Device Name: NEOTONUS MODEL 1000 MUSCLE STIMULATOR SYSTEM

Indications For Use:

The NEOTONUS Model 1000 Muscle Stimulator System is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in women.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973096