K042881

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PHOENIX
MEDICAL DEVICES

510(k) Summary for the PMD-2000 Interferential Stimulator

1. Sponsor

Phoenix Medical Devices, LLC
620 Newport Center Drive, Suite 1100
Newport Beach, Ca 92660

Registration Number: 3004620982

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Date Prepared: September 15, 2004

2. Device Name

Proprietary Name: PMD-2000 Interferential Stimulator
Common/Usual Name: Electrical Muscle and Nerve Stimulator
Classification Names: Interferential Current Stimulator, Powered Muscle Stimulator
Classification Panel: Physical Medicine
Panel/Product Code: 890.5850 / IPF and LIH

3. Legally Marketed Device to Which Equivalence is Claimed

Proprietary Name: CS3101 Interferential Stimulator
Common/Usual Name: Electrical Muscle and Nerve Stimulator
Classification Names: Interferential Current Stimulator, Powered Muscle Stimulator
Classification Panel: Physical Medicine
Panel/Product Code: 890.5850 / IPF

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4. Intended Use

The PMD-2000 Interferential Stimulator is a multifunction device intended to be used for muscle and nerve stimulation using either of its two therapy modes, Interferential Current Stimulation or Neuromuscular Electrical Stimulation.

In the Interferential Current Mode the PMD-2000 is indicated for the following conditions:

- Symptomatic relief of acute pain
- Symptomatic management and relief of chronic pain
- Adjunctive treatment for the management of post traumatic and Post-surgical pain

In the Neuromuscular Stimulation Mode, the PMD-2000 is indicated for the following conditions:

- 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; and
- Maintaining or increasing range of motion.

5. Device Description

The PMD-2000 Interferential Stimulator is a battery or AC wall adapter powered device intended for clinic, and outpatient use. Once prescribed by a physician it gives the clinician a variety of electrotherapy modes to treat a range of indications. The PMD-2000 is designed for clinician and patient ease of use and provides safe and effective dispensing of the desired electrotherapy treatment. The PMD-2000 incorporates the following features:

- Two independent stimulation channels, which provide true interferential current and neuromuscular stimulation.

- Continuous or pulsed stimulation. Various sweep and ramp times.
- Adjustable amplitude and frequency
- Fifteen preset therapy protocols
- Pause button to allow temporary suspension of treatment and a resume button to allow the resumption of treatment. When a treatment session is paused, the timer does not countdown. Upon resumption of treatment, the timer resumes its countdown and the amplitude (intensity) is reset to zero.
- Easy to connect, easy to handle, patient lead wire/cable assembly with a "one way" connector and color coded lead wires contribute to improved patient experience and improved therapy outcomes.
- Timed therapy sessions.
- Double A (AA) battery system accommodates standard alkaline, NiCad and Nickel Metal Hydride batteries.
- The PMD-2000 user interface incorporates a 16 character (8x2) Liquid Crystal Display (LCD) and tactile switches for menu navigation.

6. Basis for Substantial Equivalence

The PMD-2000 is substantially equivalent to the legally marketed device and is similar in design, features and function and provides the intended therapy in a safe and effective manner. Both devices offer near-identical preprogrammed treatment protocols and the clinician or patient can choose one or more of these pre-set options.

Bench testing was performed on the marketed device and the PMD-2000 and the therapy output and performance characteristics for both units was substantially equivalent.

7. Differences Between the Marketed Device and the PMD-2000

The PMD-2000 incorporates several improvements over the legally marketed device, including:

- Simplified battery system. There is no need to exclusively use rechargeable AA batteries. This provides great freedom of mobility and battery choice to the user. This feature greatly reduces therapy down time. The simplified battery system also lowers the weight of the device by 50% and results in a more economically priced device.
- Very low operating temperatures due to the removal of the battery charging system.

- Improved safety due to the device software and hardware working together at several "checkpoints" to protect the patient from unsafe energy levels.

- Greatly simplified user interface with a minimum number of steps to begin therapy treatment.

- Easy to read interface screens of available options and settings.

- Large "Pause" and "Stop" buttons on the interface ensure quick suspension of treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2004

Phoenix Medical Devices, LLC
c/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue S.E.
Grand Rapids, Michigan 49548

Re: K042881
Trade/Device Name: PMD-2000 Interferential Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: November 3, 2004
Received: November 5, 2004

Dear Mr. Devine:

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) 276-0115. 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/dsma/dsmamain.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

510(k) Number (if known): K042881

Device Name: PMD-2000 Interferential Stimulator

Indications for Use:

Interferential Current Mode: Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post surgical and post traumatic pain.

Neuromuscular Stimulator Mode: Relaxation of muscle spasm, increasing local blood circulation, maintaining and increasing range of motion, preventing or retarding disuse atrophy, muscle re-education, and immediate post surgical stimulation of calf muscles to prevent venous thrombosis.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 and Neurological Devices

510(k) Number K042881