K981976

NOV 25 1998

Microcurrent Research, Inc.

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Phoenix, AZ USA 85028
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510K Summary

K 981976

From: Microcurrent Research, Inc. (see letterhead)
Submitter: Paul Davis, President
Submitted August 28, 1998

Device: Commercial name: Acutron Mentor
Classification: TENS device (transcutaneous electric nerve stimulator)

Legally marketed predicate devices:

1) Acutron Multiwave 911E: Manufactured by Microcurrent Research, Inc., Phoenix, AZ
FDA 510K #K880042B

2) Theratouch 4.7: Manufactured by Rich-Mar, Inola, OK
FDA 510K #K932868

3) Dynatron 550: Manufactured by Dynatronics, Salt Lake City, UT
FDA 510K #K941577

Description of device:

The Acutron Mentor is an electromedical device of advanced design that is capable of delivering precisely modulated currents of variable intensity, frequency, polarity, modulation and waveform configuration to the soft tissues and peripheral nerves of the body via transcutaneous stimulation. The Acutron uses a large, easy to read LCD screen for all treatment set-up and monitoring, which greatly speeds and simplifies usage. The Acutron has four independently controlled and electrically isolated output channels. The multiple outputs and variations of current configuration allow the user many invaluable options of affording comfortable and effective treatment to his or her patients. These are:

Conventional pulsed milliamp stimulator

Advanced microcurrent stimulator

Interferential stimulator with classic milliamp and microcurrent options

Russian current stimulator with fixed 2500 Hz carrier frequency with 50 Hz bursts

Until the release of the Acutron, a practitioner would usually have to purchase several different instruments to fulfill all of these treatment styles.

Although electrical stimulation (ES) has now been in common use for pain management for over three decades, there are still differing opinions on exactly how it works, or exactly how to apply it. The Gate Control theory of pain postulated in 1965 by Melzack and Wall offered sufficient theoretical framework for the development of this technology. The Gate Theory states that externally applied electrical signals from a TENS unit can create enough of an input overload to the dorsal horn of the spinal cord via the C nerve fibers that there is less perception of pain signals through the slower A nerve fibers.

The Acutron Mentor offers two current ranges and several waveforms and current modulations. All parameters can be customized prior to or during treatment. The Acutron's two current ranges are milliamperage (0 - 60 mA) and microamperage (25 - 600 μA). Each output channel has its own treatment timer, offering many preset time options ranging from 4 seconds to 20 minutes, and continuous. Each channel also offers a conductivity test mode, with its own separate conductivity display on the LCD display. The purpose of this feature is to insure good conductive interface between the electrodes and the patient's skin at all times prior to and during treatment.

The device offers two methods of therapeutic current application- probe and pad electrodes. Pad channels utilize conventional TENS pads as interface with the patient's skin. Probe electrodes have wells in the probe tips to accept cut-off tips of cotton swabs, which are wetted for creating a conductive interface. The Acutron Mentors four channels are designated by letters A, B, C, and D. Channels A, B and C each stimulate a set of two TENS pads. Channel D is a dual channel which can be used to power either a fourth set of TENS pads or a set of two probe electrodes (not both). Due to the advanced design of the Acutron Mentor, the channels can be programmed together or separately. If programmed separately, each channel can output a completely different set of parameters such as frequency, waveform, modulation, polarity and treatment time. This feature can allow for the simultaneous treatment of several patients with differing needs.

The Acutron Mentor design is composed of four separate circuit boards. There is one logic board, which contains the LCD display and includes the main processors and memory chips. There is one power supply board, which receives 18 volts DC current from the external AC/DC adapter and converts this to all the necessary voltages needed for logic, therapeutic currents and communications. There are also two output channel boards, each of which contains the circuitry for two of the output channels. This design allows for easy servicing and upgrades, and maintains strict electronic isolation betwen the four channels, and between the power supplies and output circuitry. The Acutrons chassis is made of rugged custom molded ABS plastic, and all external controls and jacks are electronically isolated from AC mains and current outputs.

Intended use of device

The intended use of the Acutron Mentor is for relief of chronic intractable pain, some types of acute pain, and postoperative pain. It is applicable for a wide range of patients with pain, except those for which its use if contraindicated. Contraindications for use are reproduced in the 510K submission K981976 in Section 11.0, preface pages 1 - 2. These include contraindications or cautions for patients with cardiac pacemakers, who are pregnant, are using electronic monitoring equipment, or with sensitive skin. It is also vital to obtain an accurate diagnosis of the cause of a patient's pain concurrent with TENS device use so that the overall condition can be addressed.

Comparison of technological characteristics

There are many similarities, and some important differences, between the old and new model Acutron devices. These are listed below. The old model will be referred to as "Old" and the new model "New":

A. Similarities

1) Combination of digital and analog electronic design, utilizing A-D converters, isolation transformers, and microprocessor controlled output voltages

2) Use of double sided PC board(s)

3) Four isolated output channels

4) Ability to switch between milliamp and microamp outputs on channels.

5) Conductivity monitoring on each output channel

6) Ability by user to modify waveform, polarity, intensity, modulation, and treatment time

7) Rechargeable battery for portabiity of unit

8) Many circuits and components in the output areas of the circuit boards are the same or very similar between the two devices

9) Two types of electrodes - TENS pads and probe electrodes with cotton swab or metal tip contacts

B. Differences

1) Chassis: Old- Metal chassis, New- molded ABS plastic chassis

2) User interface: Old- manual knobs and switches for all adjustments. New- all set-up and adjustments done through pressing buttons around LCD display and depressing and turning Command Knob

3) Power supply: Old- External charger charged two rechargeable batteries, unit could only run off batteries. New- External AC/DC adapter directly powers the Power Supply PCB, secondarily trickle charging rechargeable backup battery. Please see additional information in this package, page 3, for safety information about new unit. In summary, through double fusing, transformer isolation, double sense resistors, and current limiting surge protection, the new unit is at at least as safe as the old unit, probably more so.

4) Output currents: New unit offers several additional waveforms and modulations requested by our customers. The most significant new offering is sine wave milliamperage in the 2500 and 4000 Hz ranges, respectively, for Russian stimulation and interferential currents.

5) Programmability: Old- User can preprogram one set of "basic" parameters. New- user can preprogram up to 40 sets of treatment parameters, storing them in memory

6) Output channels: Old- three channels for pad output, one for probe output only. New- Probe output offered on channel D, however, all four channels can be used for pad output if desired

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

Mr. Paul Davis
President
Microcurrent Research, Inc.
3810 East Desert Cove Avenue
Phoenix, Arizona 85028

Re: K981976
Trade Name: Mentor 961 Acutron TENS
Regulatory Class: II
Product Code: GZJ
Dated: August 26, 1998
Received: September 2, 1998

Dear Mr. Davis:

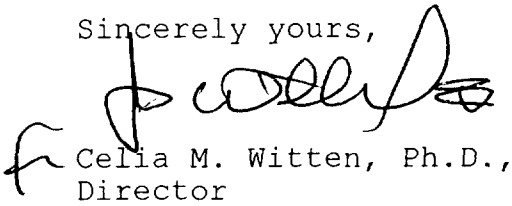
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K981976

DEVICE NAME: Acutron Mentor

INDICATIONS FOR USE:

Symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981976