K071120

MAR 13 2008

510(k) Summary
AEMED, Inc.
StimPad™ TENS System
(As required by 21 C.F.R. Parts 807.87(h) and 807.92)
Prepared: December 6, 2007

A. MANUFACTURER

AEMED, Inc.
3715 Victoria Road
West Palm Beach,
Florida 33411

B. CONTACT PERSON

Ralph Jugo
Submission Correspondent
Senior Technical Specialist
Quality First International Limited
6530 SW 49th Terrace
South Miami, FL 33155

Telephone	305-661-7005
Telefax	305-661-7005
Cellular	305-409-7791
e-mail address	ralph@qualityfirstint.com

C. DEVICE

Trade Name or Proprietary name:	AEMED StimPad™ Transcutaneous Electrical Nerve Stimulator (TENS) System (Model # 021999)
Common Name:	TENS Device
Classification Name:	Transcutaneous electrical nerve stimulator (TENS) for pain relief
Proposed Class/Device:	II
Product Code:	GZJ (21 CFR 882.5890)

D. INTENDED USE

The StimPad™ System is a transcutaneous electrical nerve stimulator (TENS) device intended for the delivery of electrical stimulation applied through the surface of patient's skin for the treatment of chronic intractable pain, and post-traumatic acute pain. The StimPad™ can be used for self treatment as well as for the treatment of others. It is a prescription use device.

E. INDICATIONS FOR USE

The StimPad™ System is indicated for the symptomatic relief of chronic intractable pain, and post-traumatic acute pain.

F. LEGALLY MARKETED PREDICATE DEVICES

The StimPad™ is substantially equivalent to the Gemore Technology Company Limited GM3 Series HV (High Voltage) TENS Model GM3X3HV (or equivalent GM323HV) cleared via 510(k) K032994, and to the Innovative Designer Products Inc. Solitens Modified cleared via 510(k) K913522 and to the Medipoint Microcurrent Therapy device cleared via K982961.

The basic design features of StimPad™ are similar to the predicate devices. The StimPad™ device and each of the predicate devices is a portable hand held battery operated micro current device that delivers electrical current by means of a direct contact point for the purpose of alleviating or relief of pain. The electrical output performance characteristics of the StimPad™ device consisting of current and voltage output, pulse frequency, pulse width, pulse duration, maximum current amplitude, time setting, and waveform are comparable and consistent with those of the predicate devices. The user controls and displays are operated in a comparable manner by the user, and the operating modes are analogous.

G. DEVICE DESCRIPTION

The StimPad™ is a non-invasive nerve stimulation therapy device that can be placed directly at the site of pain for direct electrical stimulation.

Stimulation is achieved through self-contained electrodes that are snap fit connected to the electronic components. There are no separate wires or electrode pads. The StimPad™ is powered by a self-contained three-volt lithium battery.

The StimPad™ device has pre-programmed settings for frequency (i.e. 7.1 Hz), pulse width [i.e. 47 milliseconds for the low, medium, and high intensity settings at 500 ohms, 2000 ohms, and 10,000 ohms] and the timed setting for treatment duration (4 seconds or less). The treatment duration is limited to four seconds or less of stimulation per application/treatment, and the user is not allowed to modify this setting. The intensity levels can be adjusted between low (stimulation is usually imperceptible), medium (usually the most comfortable), and high (maximum level for comfort).

A three-volt lithium battery powers the StimPad™. The life of the battery varies with the frequency of activation, repetition and ambient temperature conditions. The battery is not replaceable. Once the battery is depleted, the device ceases to function and should be disposed or returned to the manufacturer.

H. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The StimPad™ is substantially equivalent to the predicate device for the following reasons:

- It has essentially the same indications for use and intended use as the predicate devices consisting of the Gemore Technology Company Limited GM3 Series HV (High Voltage) TENS Model GM3X3HV (or equivalent GM323HV) cleared via 510(k) K032994, and the Innovative Designer Products Inc. Solitens Modified cleared via 510(k) K913522, and the Medipoint Microcurrent Therapy device cleared via K982961.
- The StimPad™ also uses the same fundamental technology and operating principles as the Gemore Technology Company Limited GM3 Series HV (High Voltage) TENS Model GM3X3HV (or equivalent GM323HV) cleared via 510(k) K032994, and the Innovative Designer Products Inc. Solitens Modified cleared via 510(k) K913522, and the Medipoint Microcurrent Therapy device cleared via K982961. The StimPad™ device and each of the predicate

devices are portable hand held battery operated micro current devices that delivers electrical current by means of a direct contact point for the purpose of alleviating or relief of pain.

- The basic design features of StimPad™ are similar to the predicate devices. The electrical output performance characteristics of the StimPad™ device are comparable and consistent with those of the predicate devices and there is overlap in the performance characteristics of the StimPad™ device with those same performance characteristics of the predicate devices. The user controls and displays are operated in a comparable manner by the user, and the operating modes are analogous.

I. SUMMARY OF TESTING PERFORMED

As is the case with the predicate device, the StimPad™ device was subjected to electrical safety and electromagnetic compatibility testing and was found to be in compliance with the requirements of the standards IEC 60601-1:1988 and IEC 60601-1-2:2001 respectively. Conformity with the requirements of these main standards supports the claim and demonstrates that the StimPad™ device is substantially equivalent to the predicate devices. Design Verification testing to characterize and assure consistent electrical output performance and comparability to the predicate devices was also successfully performed in association with the software validation testing activities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AEMED, Inc.
% Quality First International Limited
Mr. Ralph Jugo
Senior Technical Specialist
6530 SW 49th Terrace
South Miami, FL 33155

MAR 13 2008

Re: K071120
Trade/Device Name: AEMED StimPad™ Transcutaneous Electrical Nerve
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: December 13, 2007
Received: December 14, 2007

Dear Mr. Jugo:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 1(a)
Revised Indication for Use Page

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K071120

Device Name: AEMED StimPad™ TENS System

Indications For Use:

The StimPad™ TENS System is indicated for the symptomatic relief of chronic intractable pain, and post-traumatic acute pain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for aem

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Prescription Use ___X___ **510(k) Number** K071120 OR Over-The-Counter Use _____
(Per 21 CFR 801.109)