DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 18, 2014

Aemed, Inc.
c/o Rachid Hattab
Quality First International
Suites 317/318 Burford Business Centre
11 Burford Rd.
Stratford, London, E15 2ST
United Kingdom

Re: K142686
Trade/Device Name: StimPad OTC
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: August 21, 2014
Received: September 22, 2014

Dear Mr. Hattab:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142686

Device Name
StimPad OTC

Indications for Use *(Describe)*
The StimPad OTC is indicated for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household work activities.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

As required by 21 CFR 807.87(h) and 807.92

Date Prepared: 16 September 2014

A. 510(k) OWNER / SUBMITTER

Name:	**AEMED, Inc**
Address:	**4 Turtle Grove Lane** **Village of Golf** **Florida** **33436** **United States of America**

B. CONTACT INFORMATION

Name:	**Rachid Hattab**
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e-mail Address:	**rachid@qualityfirstint.com**

C. DEVICE

Trade name or Proprietary name:	**AEMED StimPad® OTC (Model #012011)**
Common Name:	**TENS Device for OTC Use**
Classification Name:	**Transcutaneous electrical nerve stimulator for pain relief intended for Over the Counter Use**
Classification:	**II**
Regulation / Product Code:	**21 CFR 882.5890 / NUH**

D. LEGALLY MARKETED PEDICATE DEVICES

AEMED, Inc. StimPad® TENS	Cleared *via* K071120 for prescription use Product Code: GZJ (21 CFR 882.5890)
Hi-Dow International, Inc Powered Muscle Stimulator	Cleared *via* K102598 for over the counter use Product Code: JQ-5C (21 CFR 882.5890)

E. INTENDED USE

The StimPad® OTC is a transcutaneous electrical nerve stimulator (TENS) device intended to deliver electrical stimulation applied through the surface of a user's skin to relieve pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities. The StimPad® OTC is an over the counter device to be used for self-treatment.

F. INDICATIONS FOR USE

The StimPad® OTC is indicated for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.

G. DEVICE DESCRIPTION

The StimPad® OTC 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® OTC is powered by a replaceable, 3 volt Lithium battery (CR2032).

The StimPad™ device has pre-programmed settings for frequency (*ie*, 7.1 Hz), pulse width (*ie*, 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 prevented from modifying 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).

The shelf life of the StimPad® OTC is dictated by the shelf life of the electrodes used in its manufacture. These components have a shelf life of 18 months and each lot is labeled with a "use before date" by the supplier. This date is assigned to the lot of StimPad® OTC devices in which they are used.

H. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The StimPad® OTC is substantially equivalent to the predicate devices for the following reasons:

- The StimPad® OTC also uses the same technology and operating principles as the predicate devices. Both the StimPad® OTC and 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 design features of StimPad® OTC are comparable to the predicate devices. The user controls and displays are operated in a comparable manner by the user, and the operating modes are analogous.

- The StimPad® OTC and StimPad® have different indications for use and intended user populations since the former is an over the counter use device and the latter is a prescription use device. Empirical proof of substantial equivalence was not necessary in this instance since the difference between the devices is simply that StimPad® OTC is available for OTC use rather than prescription by medical practitioner. Adequacy of the StimPad® OTC for OTC use was determined by formal usability evaluation study. The study confirms that StimPad® OTC is appropriate for over the counter use.

- The StimPad® OTC and Hi-Dow International, Inc Powered Muscle Stimulator have similar indications for use and intended user populations. Both devices are indicated for the relief of pain associated with sore or aching muscles of the lower back, arms or legs due to strain from exercises or normal household and work activities. Both devices are intended for over the counter use.

Tables 1, 2 and 3 compares basic unit characteristics, output specifications and physical equivalence between the AEMED StimPad® OTC, AEMED prescription use StimPad® device and HI-Dow JQ-5C.

Table 1 Basic unit characteristics

Parameter	StimPad® OTC	Prescription Use StimPad®	Hi-Dow JQ-5C
510(k) Number	K142686	K071120	K102598
Device Name and Model	StimPad® OTC Model # 012011	StimPad® Model # 021999	Power Muscle Stimulator Model #JQ-5C
Manufacturer	AEMED, Inc	AEMED, Inc	Hi-Dow International, Inc
Device Class	II	II	II
Classification Panel	Neurology	Neurology	Neurology
Power Source(s)	3 volt Lithium battery (CR2032)	3 volt Lithium battery (CR2032)	3.75 volt DC Lithium battery
Battery rechargeable	No	No	Yes
Number of batteries	1	1	1
Battery size (mm)	Diameter=20 Height=3.2	Diameter=20 Height=3.2	
Average DC current through electrodes when device is on but no pulses are being applied (µA)	≤10	≤10	0
Number of Output Modes	3	3	6
Number of Output Channels:	1	1	2
Regulated Current or Regulated Voltage	Current	Current	Voltage

Parameter		StimPad® OTC	Prescription Use StimPad®	Hi-Dow JQ-5C
Software/Firmware/Microprocessor Control		Yes	Yes	Yes
Automatic Shut Off		Yes	Yes	Yes
Indicator Display:	On/Off Status	Yes	Yes	Yes
	Low Battery	Yes	Yes	Yes
Timer Range (minutes)		Single 4 second pulse or multiple pulses *via* manual mode (e.g. 10 deliveries or 40 seconds)	Single 4 second pulse or multiple pulses *via* manual mode (e.g. 10 deliveries or 40 seconds)	Timer can be adjusted after selecting one of the 6 modes
Compliance with Voluntary Standards		Yes	Yes	Yes
Weight (gram)		95	95	200
Dimensions (mm) [W x H x D]		120 X 73 X 35	120 X 73 X 35	114 x 71 x 10
Housing Materials and Construction		Polycarbonate	Polycarbonate	ABS
Portable		Yes	Yes	Yes
User friendly		Yes	Yes	Yes

Table 2 Output Specifications

Parameter		StimPad® OTC	Prescription Use StimPad®	Hi-Dow JQ-5C
Waveform (e.g., pulsed monophasic, biphasic)		Pulsed, Monophasic	Pulsed, Monophasic	Pulsed, Monophasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular	Rectangular
Maximum output voltage (volts) (+/- 10%)		122.50@500Ω	122.50@500Ω	62.4@ 500
		159.00@2 kΩ	159.00@2 kΩ	79.2@2.2K
		159.99@10 kΩ	159.99@10 kΩ	84@10K
Maximum output current (mA) (+/- 10%)		0.25@500Ω	0.25@500Ω	124.8@500
		0.08@ 2 kΩ	0.08@ 2 kΩ	39.6@2.2K
		0.02@10 kΩ	0.02@10 kΩ	8.4@10K
Duration of primary (depolarizing) phase (ms)		92	92	N/A
Pulse duration (µsec)		222-264	222-264	16300~781000
Frequency (Hz)		7.1	7.1	61.3
For multiphasic waveforms only:	Symmetrical phases?	No	No	No
Net Charge per pulse (µC) at 500 Ω (If zero, state method of achieving zero net charge)		40.9	40.9	0, balanced waveform
Maximum Phase Charge (µC) at 500 Ω		12.066	12.066	17.92
Maximum Current Density (mA/cm²) at 500 Ω		12.066	12.066	9.92
Maximum Average Current (mA) at 500 Ω		0.25	0.25	N/A

Parameter		StimPad® OTC	Prescription Use StimPad®	Hi-Dow JQ-5C
Maximum Average Power Density, (W/cm²) at 500 Ω (W/cm²), (using smallest electrode conductive surface area)		0.06033	0.06033	2.72
Burst mode (i.e., pulse trains):	(a) Pulses per burst	29	29	N/A
	(b) Bursts per second	4	4	N/A
	(c) Burst duration (sec)	Minimum of 500+ four (4) second stimulations on Low and 250+ four(4) second stimulations on High	Minimum of 500+ four (4) second stimulations on Low and 250+ four(4) second stimulations on High	N/A
	(d) Duty Cycle: Line (b) x Line (c)	2000- Low 1000-High	2000- Low 1000-High	N/A
ON time (seconds)		4	4	5 (M2, M3 and M4)
OFF time (seconds)		The device remains off until the top is depressed against the skin	The device remains off until the top is depressed against the skin	3 (M2) 2 (M3 and M4)

Table 3 Overview of selected properties

Parameter	StimPad®		
	OTC	Prescription Use	Hi-Dow JQ-5C
510(k) Number	K142686	K071120	K102598
Sterility	Non-sterile	Non-sterile	Non-sterile
Packaging	Packaged in a 13.5 cm x 22 cm foil zip lock pouch	Packaged in a 13.5 cm x 22 cm foil zip lock pouch	Box packaging with JC-QC unit, 1 set of small single sided adhesive electrode pad, large single sided adhesive pads, XL single sided adhesive electrode pads, 2 electrode wire, AC/DC adaptor, application acupoints chart and pad holder
Biocompatibility	The main user contact materials are hydrogel disks	The main user contact materials are hydrogel disks	Biological safety conformity compliance

Parameter	StimPad®		
	OTC	Prescription Use	Hi-Dow JQ-5C
	and polycarbonate housing material with a limited contact duration (i.e., less than 24 hours). Both items are biocompatible Evaluations per ANSI/AAMI/ISO 10993-1:2009. "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing" and the FDA Blue Book Memorandum # G95-1 regarding biocompatibility, were performed	and polycarbonate housing material with a limited contact duration (i.e., less than 24 hours). Both items are biocompatible Evaluations per ANSI/AAMI/ISO 10993-1:2009. "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing" and the FDA Blue Book Memorandum # G95-1 regarding biocompatibility, were performed	performed according to EN ISO 10993-1:2009
Software	The device contains a software controlled microprocessor. Evaluations per the "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices" (issued May 11, 2005), were performed. • The level of concern considered minor • No failure modes and associated potential hazards that could occur with the device are software related	The device contains a software controlled microprocessor. Evaluations per the "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices" (issued May 11, 2005), were performed. • The level of concern considered minor • No failure modes and associated potential hazards that could occur with the device are software related	The device contains a software controlled microprocessor. Presumed software conformity for software contained in medical devices as device is 510k approved
Electrical Safety and Electromagnetic Compatibility	Evaluations per UL® 2601-1 and CSA 22.2 No. 601.1M90 were performed U.S. Federal Communication Commission (FCC) Code of Federal Regulations (CFR), Title 47 – Telecommunication, Part 15 – Radio Frequency Devices, Part B – Unintentional Radiators. Section 15.109(b) Radiated Emissions Class B limits,	Evaluations per UL® 2601-1 and CSA 22.2 No. 601.1M90 were performed U.S. Federal Communication Commission (FCC) Code of Federal Regulations (CFR), Title 47 – Telecommunication, Part 15 – Radio Frequency Devices, Part B – Unintentional Radiators. Section 15.109(b) Radiated Emissions Class B limits,	Compliance claimed with EN 60601-1, EN 60601-1-2, EN ISO 14971:2009, EN 60601-2-10:2000 + A1:2001

Parameter	StimPad®		
	OTC	Prescription Use	Hi-Dow JQ-5C
	and the standard IEC 60601-1-2:2007 "Medical electrical equipment Part 2. Collateral Standard: Electromagnetic compatibility" were performed. • The microcoulombs observed at all settings do not raise any safety concerns • Leaking current testing requirements fulfilled • All of the following passed evaluation: Marking Durability, Enclosure Mechanical Strength, Drop Impact, Temperature, Leakage Current, Dielectric Voltage Withstand, Humidity, Cleaning, Mold Stress Relief, Abnormal • Device conforms to FCC Class B requirements • EMC evaluations fulfilled requirements	and the standard IEC 60601-1-2:2007 "Medical electrical equipment Part 2. Collateral Standard: Electromagnetic compatibility" were performed. • The microcoulombs observed at all settings do not raise any safety concerns • Leaking current testing requirements fulfilled • All of the following passed evaluation: Marking Durability, Enclosure Mechanical Strength, Drop Impact, Temperature, Leakage Current, Dielectric Voltage Withstand, Humidity, Cleaning, Mold Stress Relief, Abnormal • Device conforms to FCC Class B requirements • EMC evaluations fulfilled requirements	
Bench Performance Testing	Evaluations of the electrical signal delivered and the conductive media performed. Replacement of electrodes after 20 four second stimulations recommended	Evaluations of the electrical signal delivered and the conductive media performed. Replacement of electrodes after 20 four second stimulations recommended	Presumed bench performance testing performed as the device is 510k approved

I. SUMMARY OF TESTING PERFORMED

Development and testing identified in this submission were actually performed on the prescription use StimPad® (K071120 refers). Results and conclusions of the prevailing development tests are applicable to the OTC variant of the device. Electrical safety and electromagnetic compatibility properties demonstrated by formal test confirm StimPad® OTC remains in compliance with the requirements of AAMI ANSI 60601-1:2005 and AAMI ANSI IEC 60601-1-2:2009 standards, respectively. Therefore, evidence of tests against the standards supports the

claim and demonstrates that the StimPad® OTC device is substantially equivalent to the prescription use StimPad®. Other than cosmetic label changes and the extension of the device intended purpose to encompass OTC use, no other changes in specification of a significant nature have been introduced. Therefore, prevailing design qualification tests to characterize and assure consistent electrical output performance as well as successfully performed software validation testing activities remain current and valid, thereby assuring comparability to the prescription use StimPad®. Furthermore, performance of the usability evaluation study confirmed that StimPad® OTC is appropriate for over the counter use.