K091875

510 (K) Summary

In accordance with requirements of 21 CFR 807.92(c)

June 19, 2009

The Assigned 510K number: 091875

1. Submitter Name: AMM Marketing LLC

2. Owner: AMM Marketing LLC EIN # 26-3986255

DEC - 7 2009

3. Preparer: Tzvi Milshtein

4. Address: 4652 Coral Ridge Drive, Coral Springs Florida 33076

5. Tel: 954- 323 2808 Fax 954- 780 7109

6. Contact Person: Tzvi Milshtein

7. Email: ammmarketingllc@gmail.com

8. Device name - E-pulse model UH 900, common name: Electro Acupuncture Device. Classification code : BWK

9. The indication for use of the E-pulse is an electro acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the state.

10. The legally marketed device which E-pulse is claiming equivalence to is the P-Stim

11. Miniaturized, battery powered unit designed to administer auricular point stimulation treatment over a 96 hour period. The device is on for 3 hours, then off for 3 hours. It has a pre-programmed micro-processor as to frequency, pulse and duration for the stimulation of the auricular acupuncture points.
The device itself is applied on the neck, below the ear with the integrated self-adhesive electrode patch.
The voltage source is from the three batteries 1.4 volts (each). The device has different frequency modes and waveform modes. The wires from the device are connected to the acupuncture needles simply by positioning and snapping a plastic ring over the semi-permanent acupuncture needles.

The software for each device is pre-configured during manufacturing and may not

be accessed by either the user or the practitioner.
Safety features are incorporated into the device to reduce possibility of misuse.

The software used in this unit is considered firmware since it resides within an 80C51 type microprocessor hardware. It resides in 1 k byte-erasable Flash code memory organized into 256-byte sectors and 16-byte pages

The program language used is microprocessor adapted C-code.
Internal timers are being employed to establish pulse width timing, pulse interval and pulse cycle. The code is optimized to reduce power consumption. There are no Interface Requirements. The code consists of a single loop. No operating system is involved. No Off-the Shelf software is used.

A watchdog timer is employed to ensure proper code execution, It is designed to shut the unit down and return all outputs to zero if the output pulse exceeds 2 ms. The unit will remain in shut down mode as long as power is applied.

Software capable was created to be generating a pulse stream output on two Output pins of the microprocessor.

The pulse stream is to consist of a repetitive 1.1 ms +/- 10% wide positive and one minute later a 1.1 ms +/- 10% wide negative pulse.
The pulse train is to continue for 3 hours after which it is to shut down for 3 hours. This cycle is to continue until the battery is run down or 96 hours have expired have been expired.
The watchdog timer is to be used to reset the outputs to zero and shut the unit down. The code is to be structured for minimum power consumption

Output: (Load impendence range 1kΩ to 10K) max. 4.2V, Impulse interval 1100ms +/- 10%,, Impulse width 1.1ms +/- 10%, (1.1Hz / 1.1ms / bipolar), max possible total duration of treatment 4 x 24 hours. The amplitude of the output signal diminishes in proportion to battery voltage
Protection level: IP 20 Type B
Duty type: approx. 3h duty / 3h at rest
Weight incl. battery: 4g | Dimensions: 23 x 8 mm
Needle Dimensions: 1.3 mm width x 3.1 mm length

12. Substantial equivalence is claimed based upon a comparison of the E-pulse To the P-stim, since both devices have the same intended use and similar operating principles . Both devices are electrical nerve stimulators with a single output channel and mode. Also, they have similar pulse width and frequencies. Both use a conductive gel product between the electrode and the patient's skin. Technical differences do not affect the safety or efficiency of the product.

Predicate Product Comparison Table

Similarities

Manufacturer	AMM Marketing LLC	NeuroScience Therapy Corp Biegler
Trade name	E-pulse	P-Stim
K #	91875	50123
Indication for Use	The indication for use of the E-pulse is an electro acupuncture device for use in the practice of acupuncture by qualified practitioner of acupuncture as determined by the state	The indication for use of the E-pulse is an electro acupuncture device for use in the practice of acupuncture by qualified practitioner of acupuncture as determined by the state
Device Description	Battery powered unit designed to administer auricular point nerve stimulation treatment for pain therapy over a 96 hour period via electrical pulsing the device is on for 3 hours then off for 3 hours the device is controled by a micro processor	A micro stimulation appliance for pain therapy micro processor controled,it generates a low frequency and continunal electrical pulse which is transmitted to the nerve endings of the ear it allowes continues therapy over several days
Target Population	Patients having acute or chronical pain	Patients having acute or chronical pain
Human Factors	To be applied by a qualified practitioner of acupuncture	To be applied by an acupuncturer
Where Used	At the clinic and at home	At the clinic and at home
Performance	Monophasic pulses width at 1mS at 1Hz frequency Performance testing was performed and all tests show satisfactory results	Monopahsic pulses at 1mS rectangular 1Hz Performance testing was performed and they show satisfactory results
Software Based	Yes	Yes
Duration	96 Hours	96 Hours

Differences

Manufacturer	AMM Marketing LLC	NeuroScience Therapy Corp Biegler
Trade name	E-pulse	P-Stim
K #	91875	50123
Semi Permanent needles	Titanium hook shaft	Titanium straight shaft
ECG	shelf item by ConMed	Custom
Shape	Round 23mm	Eliptic 42mm by 20mm

Technological Characteristics of the E-pulse does not raise any new type of safety and effectiveness questions. The operating technology, the method of pulsing transmission via wires, the micro processing, electrical power source, wire termination transmission through similar acupuncture needles are all substantially equivalent.

13. The system-level test protocol consists of the measurements of the specified test parameters outlined in the Description above using an oscilloscope.

The design is considered to pass if the test results are within the specifieds limits.

Perfomance nonclinical data

Nonclinical testing: The device was tested in accordance with the tests specified in IEC 60601-2-10:2000 , 60601-1-2:2007 , 60601-2-10:1987

and the EMC & EMI lab testing

1. PULSE TIMING. Verify that the output pulse timing is consistent with the design objective.
2. PULSE LEVEL. Verify that the output pulse voltage level and waveform is consistent with the design objective.
3. PULSE CYCLE. Verify unit output pulse ON and OFF cycle and end of life time interval.
4. EMC. To ensure that the output pulse stability is maintained independent of the applied Rf-radiation according to IEC601-2-10 paragraph 36, Test 1 and paragraph 36.202 Amendment 1 IEC 60601-2-10 1987 Immunity.
5. EMI. EMI test to ensure that the unit complies with paragraph 36.201 Amendment 1 IEC 60601-2-10 1987 Emissions.

1. PULSE TIMING. Output pulse timing measurement of the unit under (UUT) test were taken with the oscilloscope and tabulated in output specifications
2. PULSE LEVEL. Load resistors as per table 2 have been attached to the output leads of the unit under (UUT) test, output pulse voltage readings taken with the oscilloscope.
3. PULSE CYCLE. The unit operation was observed over the time period specified and output pulse ON and OFF cycle and end of life time interval results recorded in device wave forms.
4. EMC. The methods applied were in accordance with IEC601-2-10 paragraph 36, Test 1 and paragraph 36.202 Amendment 1 IEC 60601-2-10 1987 Immunity. EMI. The EMI test methods applied were in accordance with paragraph 36.201 Amendment 1 IEC 60601-2-10 1987 Emissions and CISPER 11.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AMM Marketing LLC
c/o Tzvi Milshtein
Manager
4652 Coral Ridge Drive
Coral Springs, FL 33076

DEC - 7 2009

Re: K091875
Trade/Device Name: E-PULSE, model UH900
Regulation Number: n/a
Regulation Name: n/a
Regulatory Class: Class II
Product Code: BWK
Dated: October 20, 2009
Received: October 23, 2009

Dear Mr. Milshtein:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091875

Device Name: E-pulse, Model UH900

Indications For Use:

E-pulse is an electro-acupuncture device for use in the practice of Acupuncture by qualified practitioners of acupuncture as determined by the state.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091875