K080221

SEP 09 2008

# 510 (k) SUMMARY


**Submitter's Name:** Helio Medical Supplies, Inc.
**Address:** 606 Charcot Avenue
San Jose, CA 95131

**Telephone:** 408-433-3355

**Fax:** 408-433-5566

**Contact person:** YUKUO HSU


**Device Name:**
Proprietary Name: EA Stimulator
Common Name: TENS unit
Classification Name: Transcutaneous Electrical Nerve Stimulator (21 CFR 882.5890, Class II)

**Predicate Device Information:**
Legally marketed device for substantial equivalence comparison is ES-160 (K051020)

**Description of Device:**
EA Stimulator is a battery powered TENS, which is used in the treatment of chronic, acute, and post-surgical pain. The device contains a printed circuit board, independent intensity controlled channels, and Microcurrent-Milliampere Switches. It also has windows, display frequency, pulse width, and time settings. The device has different stimulation frequency modes with different selected waveforms. EA Stimulator uses self adhesive electrodes and has energy saving feature that automatically turns off if the device has no activity for 5 minutes or when a treatment session is completed.

**Intended use of the Device:**
This device is designed to be used in the treatment of chronic, acute, and post-surgical pain. A physician can select different frequency modes, waveform modes, switch Microcurrent-Milliampere mode, and adjust the intensity to treat his/her patients.

**Technological Characteristics:**
EA Stimulator uses four or eight 1.5volt batteries and has a stimulation mode for the treatment.

**Performance Summary:**
The device conforms to applicable standards includes EN60601-1-2:2001/A1:2006, IEC 60601-1-2:2001/A1:2004, IEC 60601-1 / EN60601-1, IEC 60601-2-10 / EN60601-2-10.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 09 2008

Helio Medical Supplies Inc.
% Mr. Yukuo Hsu
Quality System Manager
606 Charcot Avenue
San Jose, California 95131

Re: K080221
Trade Name: EA 2/2 Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief.
Regulatory Class: Class II
Product Code: GZJ
Dated: September 3, 2008
Received: September 4, 2008

Dear Mr. Hsu:

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.

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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

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

Enclosure

SEP 0 9 2008

# Indications For Use

510(k) Number (if known): K080221

Device Name: EA Stimulator

Indications For Use:

This device is designed to be used in the treatment of chronic, acute, and post-surgical pain.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

**510(k) Number** K080221