510 k: K090922

JUN - 5 2009

Empi®

510(k) Summary

510(k) Owner's Name: Empi, Inc.
Address: Clear Lake Industrial Park
Clear Lake, SD 57226

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Contact person: Sandra Walrod, Regulatory Affairs Associate

Date prepared: March 30, 2009

Trade name: Empi Active Transcutaneous Nerve Stimulator
Common name: TENS

Classification name: Transcutaneous Electrical Nerve Stimulator (21 CFR 882.5890)

Product Code: GZJ, NYN

Classification: II

Predicate device(s): Empi SELECT Model 4600 Transcutaneous Nerve Stimulator K061650

Device Description:

The Empi Active Transcutaneous Nerve Stimulator is a battery powered single-function device intended to provide clinicians with a TENS Simple Modulated Pulse (SMP) therapy. This device is intended to be easy to use without the hassle of configuration. Simply turn the device on and increase or decrease the intensity. It is a single-function electrotherapy device with one mode of treatment that allows for Transcutaneous Electrical Nerve Stimulation (TENS).

Intended Use:

The Empi Active Transcutaneous Nerve Stimulator is indicated for use as a Transcutaneous Electrical Nerve Stimulation (TENS) device. This is the same indication as for the Empi SELECT device. The Empi Active Transcutaneous Nerve Stimulator incorporates a TENS

Simple Modulated Pulse mode for relief and management of chronic and intractable pain. The Empi SELECT incorporates the very same TENS Simple Modulated Pulse stimulation treatment mode for relief and management of chronic and intractable pain. Both devices are prescription devices to be used under the direction of a medical professional. Both devices are designed to be used in a clinic setting or by the patient at home. Therefore, the intended use of the Empi Active Transcutaneous Nerve Stimulator are the same as those for the Empi SELECT.

Comparison to predicate:

This submission is intended to demonstrate that the Empi Active Transcutaneous Nerve Stimulator has the same intended use as the predicate device and that there are no changes to the fundamental scientific technology and the basic considerations described in the guidance.

The Empi Active Transcutaneous Nerve Stimulator is indicated for use as a Transcutaneous Electrical Nerve Stimulation (TENS) device. This is the same indication as for the Empi SELECT device. The Empi Active Transcutaneous Nerve Stimulator incorporates a TENS Simple Modulated Pulse mode for relief and management of chronic and intractable pain. The Empi SELECT incorporates the very same TENS Simple Modulated Pulse stimulation treatment mode for relief and management of chronic and intractable pain. Therefore, the indications for use of the Empi Active Transcutaneous Nerve Stimulator are the same as those for the Empi SELECT. Both devices are prescription devices to be used under the direction of a medical professional. Both devices are designed to be used in a clinic setting or by the patient at home. Therefore, the intended use of the Empi Active Transcutaneous Nerve Stimulator are the same as those for the Empi SELECT.

Non-clinical Testing:

Verification of the Empi Active Transcutaneous Nerve Stimulator includes electrical, mechanical, and software tests to show that the device meets its product specifications over a range of operating and storage conditions. Validation testing for the Empi Empi Active Transcutaneous Nerve Stimulator includes testing to show the device meets user needs according to marketing requirements.

The Empi Active device conforms to the following voluntary standards:

- UL 60601-01 Medical electrical equipment – Part 1: General requirements for safety 2003
- CAN/CSA C22.2 No.601.1-M90 with Amendment A2. 2005
- IEC60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004)

Clinical Testing:

No prospective clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance in the target markets. The Empi Active

Transcutaneous Nerve Stimulator does not differ from the predicate device in technological characteristics or intended use, where the device has a significant influence on clinical endpoints, and where prospective clinical studies would be necessary to determine safety and efficacy equivalence. The Empi Active Transcutaneous Nerve Stimulator does not fit the profile of devices that might require clinical data per FDA guidance document 95-4158.

Conclusion:

The Empi Active Transcutaneous Nerve Stimulator is substantially equivalent the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Empi, Inc.
c/o Virginia L. Conger
Director of Quality and Regulatory
205 Hwy 22 East
Clear Lake, SD 57226-0709

JUN - 5 2009

Re: K090922
Trade/Device Name: Empi Active Transcutaneous Nerve Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: May 11, 2009
Received: May 15, 2009

Dear Ms. Conger:

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic 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): K090922

Device Name: Empi Active Transcutaneous Nerve Stimulator

Indications for Use:

The Empi Active Transcutaneous Nerve Stimulator Device is used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. It is also used as an adjunctive treatment for post-surgical and post-trauma acute 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K090922

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K090922