K061650

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510(k) Summary

510(k) Owner:	Empi
Address:	599 Cardigan Rd. St. Paul, MN 55126
	JAN 2 2 2007
Phone number:	651.389.0771
Fax number:	651.638.0477
Contact person:	Carl Beaurline, VP of Global Regulatory Affairs
Date prepared:	June 7, 2006
Trade name:	SELECT® TENS System
Common name:	TENS
Classification name:	Transcutaneous Electrical Nerve Stimulator (21 CFR 882.5890, Product Code GZJ)
Classification:	II
Predicate devices:	Empi Epix VT® TENS System (K970203), Chattanooga Group Forte CPS 400 Stim and Forte CPS 200 Stim (K982828)

Device Description:

The SELECT® is a portable, dual channel TENS device with ten pre-programmed operational modes. It is powered by 3 standard AAA alkaline or rechargeable batteries. All operational modes produce the Empi Bi-Sourced® waveform. The user selects a pre-programmed mode by either pressing a Quick Select button with the picture of a body part needing treatment or by using the Program buttons to select one of ten program options. The user is able to adjust the intensity up or down. The lock mode prevents inadvertent changes to the intensity or the program option. The SELECT® is intended for use in the clinic or in the home with a prescription. A belt clip allows the patient to wear the Empi SELECT® on a belt or pants waistband. The SELECT® battery icon on the LCD will flash when the batteries need replacement. Compliance data can be retrieved by the clinician including number of sessions, average session length, and average intensity.

Intended Use:

The Empi® SELECT Transcutaneous Electrical 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.

Comparison to predicate:

The Empi SELECT® TENS System has the same indications for use as the predicate devices but the technological characteristics are different. There are no changes to the

output modes (waveforms) for the SELECT® compared to the Epix VT®. The major difference between the Epix VT® and SELECT® are user interface characteristics. The Epix VT® has a small LCD display and membrane switches for controlling and displaying adjustable settings. The SELECT® has a keymat style push button system and a larger LCD screen controlling and displaying the adjustable settings. Also, the pain scale used on the Epix VT® is removed from the SELECT® and replaced by an On/Off button and five Quick Select buttons with pictures of body parts linking to preset recommended programs already existing on the device. The Quick Select buttons are similar to the Clinical Protocols on the Chattanooga Group Forte CPS 400 Stim and Forte CPS 200 Stim. The SELECT® continues to record the number of sessions, the average session length, and the average intensity for data retrieval by a clinician.

Non-clinical Testing:

Verification of the Empi SELECT® TENS System includes electrical and mechanical tests to show that the device meets its product specifications over a range of operating and storage conditions. Validation testing for the Empi SELECT® TENS System includes testing to show the device meets user needs according to marketing requirements.

Clinical Testing:

The Empi SELECT® TENS System does not require clinical testing in order to determine substantial equivalence to the predicate devices.

Conclusion:

The non-clinical testing demonstrates that the Empi SELECT® TENS System is safe, effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2007

Empi
% Mr. Carl Beaurline
Vice President, Regulatory Affairs
599 Cardigan Road
St. Paul, Minnesota 55126

Re: K061650
Trade Name: Empi® SELECT Transcutaneous Electrical Nerve Stimulator Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ, NYN
Dated: January 22, 2007
Received: January 22, 2007

Dear Mr. Beaurline:

This letter corrects our substantially equivalent letter of January 22, 2007. 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

For

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

Enclosure

Indications for Use

510(k) Number (if known): K061650

Device Name: Empi® SELECT Transcutaneous Electrical Nerve Stimulator Device

Indications for Use:

The Empi® SELECT Transcutaneous Electrical 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)

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

510(k) Number K061650