K090866

# Traditional 510(k) Summary
## NeuroCalm Transcutaneous Nerve Stimulator (TENS) Device

OCT 21 2009

**1. Sponsor**

**NeuroMed Corporation**
29461 Troon St.
Laguna Niguel, CA 92677

Contact Person: Robert Seiple
Telephone: (940) 390 0961

Date Prepared: 15 February 2009

**2. Device Name**

| | |
|---|---|
| Proprietary Name | NeuroCalm TENS Device |
| Common/Usual Name | Transcutaneous Nerve Stimulator |
| Classification Name | Transcutaneous Electrical Nerve Stimulator for Pain Relief |

**3. Predicate Devices:**

1) Biowave Corporation's, "Homewave Neuromodulation Pain Therapy Device" PMN # K072123,
2) AEMED, Inc. "StimPad$^{Tm}$ TENS System" #K071120

**4. Intended Use**

- Symptomatic relief and management of chronic, intractable pain
- Management of post-surgical pain
- Management of post-traumatic pain.

**5. Device Description**

The NeuroCalm device is a battery-powered portable TENS device intended for the relief of chronic intractable pain and adjunctive treatment of post-surgical or post-traumatic acute pain. The device is small, portable and lightweight.

The device is available in two configurations: Model 1 and Model 2. The Model 1 configuration provides a 10-second treatment using a proprietary wave form while Model 2 provides a 35-second treatment using a slightly different waveform to alleviate pain.

The NeuroCalm TENS device is powered by a 12-volt battery. The power source provides ample power for the 10-course treatment. The device has a two-year shelf life.

Treatment is provided by passing AC and DC current through noble metal (gold) electrodes. Treatment cycles are controlled by software-controlled printed circuit board assemblies. Electrical output and waveforms are optimized depending on the treatment duration desired. A complete course of treatment consists of a 10 x 10-second treatment for Model 1 and a 10 x 35-second treatment for Model 2. After the conclusion of the tenth treatment, the device is inoperable and may be discarded (discard as one would discard a battery).

**6. Basis for Substantial Equivalence:**

NeuroMed Corporation's TENS device, Biowave's neuromodulation device and AEMED, Inc. "StimPad$^{Tm}$ TENS System are similar in intended use, design and function. All are TENS devices (of which there are over 500 cleared devices) and provide pain relief by generating small electrical currents of varying waveforms applied directly to the area experiencing pain. The proposed and predicate devices share the same regulatory classification (Class II, classification code GZJ), are battery powered, and are all software-controlled TENS units that provide the user with pain reduction. The NeuroCalm device is intended for use in pain relief. The conclusion of the technical comparison is that the NeuroCalm TENS device is substantially equivalent to the predicate devices for the indication specified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

NeuroMed Corporation
c/o Mr. Daniel W. Lehtonen
Senior Staff Engineer – Medical Devices
Intertek Testing, Services NA, Inc.
23047 E. Aurora Road
Unit B7
Twinsburg, OH 44087

OCT 21 2009

Re: K090866
Trade/Device Name: NeuroCalm TENS Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: II
Product Code: GZJ
Dated: September 9, 2009
Received: October 6, 2009

Dear Mr. Lehtonen:

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, 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): K090866

Device Name: NeuroCalm Transcutaneous Electrical Nerve Stimulator

**Indications for Use:**

The NeuroCalm Transcutaneous Electrical Nerve Stimulator Device is indicated for symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.

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



Bruce Drum

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

**510(k) Number** K090866