



USER: GARCIA, DIANE M (dmp)

FOLDER: K042912 - 8 pages (Subset of Folder)

COMPANY: NEURO RESOURCE GROUP, INC.
(NEURRESOGROU)

PRODUCT: STIMULATOR, NERVE, TRANSCUTANEOUS,
FOR PAIN RELIEF (GZJ)

SUMMARY: Product: INTERX5000

DATE REQUESTED: Mon Jan 07 11:47:39 2008

DATE PRINTED: Mon Jan 07 11:48:16 2008

PRINTER: file

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MAY 17 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Krista Oakes
Vice President, Regulatory Affairs
Neuro Resource Group, Inc.
1100 Jupiter Road, Suite 190
Plano, Texas 75074

Re: K042912
Trade/Device Name: InterX5000
Regulation Numbers: 21 CFR 882.5890
Regulation Names: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: April 14, 2005
Received: April 18, 2005

Dear Ms. Oakes:

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.

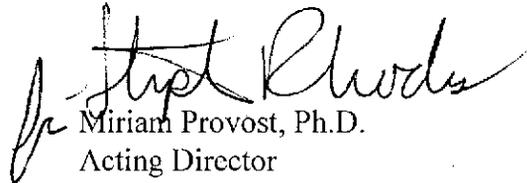
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", is written over the typed name.

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) # (if known): K042912

Device Name: InterX5000

Indications for Use:

The InterX5000 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
(21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(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 General, Restorative
and Neurological Devices**

510(k) Number K042912

APPENDIX A

**SUMMARY OF SAFETY AND
EFFECTIVENESS**



NEURO RESOURCE GROUP

510(k) Summary

Submitter Information:

Contact:

Krista Oakes
Tel: 972-438-5202
Fax: 972-401-9161

Date Prepared:

September 30, 2004

Product Name & Classification:

Classification Regulation: 882.5950, 890.5850,
Panel: Neurology, Physical Medicine
Product Code: GZJ, IPF
Trade Name(s): InterX5000

Predicate Device:

K041575 – Fenzian Treatment System
K951951 – EMPI Focus 795
K870947 – Dynatron 500 Electrical Muscle Stimulator

Description:

InterX means “Interactive”. InterX technology is designed to work by introducing very brief pulses of electricity into the tissue and immediately monitoring impedance changes as the tissue responds. Stimulation and sensing take place via a concentric electrode system that is moved over the skin surface, and a digital display enables the operator to follow the course of the treatments and adjust the output.

The InterX 5000 consists of a small handheld device in a plastic case. It is powered by one nine-volt alkaline battery. On the upper face of the machine there are two LED's, an LCD display and 5 control buttons. The underside of the machine contains two metal surfaces that form the poles of a treatment electrode. The electrodes are placed directly on the unbroken skin and do not use any conductive material or gel.

On the side of the machine is one socket for a standard 3.5mm stereo jack socket that connects to the main electrodes of the machine to an optional external electrode accessory. The device's electrodes are disabled when the optional external electrode accessory is

attached. The optional external electrode accessories only serve as an extension and allow the user to apply treatment in areas which may not be accessible by the main unit electrodes. None of the three electrode accessories intended for use with the InterX 5000 have any active electrical components.

The waveform is a high amplitude, short-duration bi-polar pulse (circuitry in the device integrates time and dosage delivered). A digital display monitors the biofeedback process in relation to the starting point, enabling the operator to track changes in the tissues being treated and make appropriate adjustments to the output characteristics if necessary. This interaction and human adjustment continues throughout the length of the InterX treatment. The result is that the body experiences a conditioned training process that enhances the body's ability to effectively reduce and manage the level of pain.

Intended Use:

The InterX5000 is indicated for:

- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain
- relaxing muscle spasms
- increasing local blood circulation
- immediate post surgical stimulation of calf muscles to prevent venous thrombosis
- muscle reeducation
- maintaining or increasing range of motion
- preventing or retarding disuse atrophy

Comparison to Predicate Devices:

- *Does the new Device have the same indications for use? Yes*
- *Does the new Device have the same Technological Characteristics? Yes*
- *Are Descriptive Characteristics precise enough to ensure Equivalence? Yes.*
- *Are Performance Data available to assess Equivalence? Yes*
- *Performance Data Demonstrate Equivalence? Yes*

A comparison matrix has been provided as part of this premarket notification.

Performance Data & Conclusions:

Performance bench testing was conducted to characterize the electrical performance of the InterX5000 as compared to published data of predicate devices.