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K050123

P-STIM
510(k) SUMMARY

(As required by 21 C.F.R. § § 807.87(h), 807.92)

Date of Submission January 17, 2005

Identification of Applicant

Applicant

NeuroScience Therapy Corp.
135 Lake St. So., #100
Kirkland, WA 98033

Contact Person

Richard J. Forsell
Corporate Secretary
425-889-4659
rforsell@ix.netcom.com

Trade or Proprietary Name P-Stim
Common Name Electro-acupuncture device
Classification Name Electro-acupuncture stimulator
Classification Unclassified

Predicate Device

The legally marketed predicate device to which the P-Stim is substantially equivalent is the Acu-Stim (K014273).

Intended Use

The P-Stim is intended for use as an electro-acupuncture device to stimulate appropriate auricular acupuncture points.

Device Description

The P-Stim is a miniaturized, battery-powered, transcutaneous electrical nerve stimulator that has a pre-programmed frequency, pulse, and duration for the stimulation of auricular acupuncture points. The device connects via three stainless steel wires to acupuncture needles that have been applied to the appropriate auricular acupuncture points. The device is powered by three zinc air batteries, each with a voltage of 1.4 V. The device is on for 180 minutes, then off for 180 minutes, for a maximum period of up to 96 hours.

Summary of Technological Characteristics

Substantial equivalence is claimed because the P-Stim has the same intended use and similar operating principles to the Acu-Stim. Both devices are transcutaneous electrical nerve stimulators with a single output channel and mode and similar pulse widths and frequencies. Both use a conductive gel between the electrode and the patient's skin. Technical differences do not affect the safety or efficacy of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Neuroscience Therapy Corp.
c/o Jan McComb, Ph. D.
ICRC, Inc.
22691 Lambert Street
Suite 517
Lake Forest, California 92630

Re: K050123
Trade/Device Name: P-Stim System
Regulation Name: Electro-Acupuncture Stimulator
Regulatory Class: Unclassified
Product Code: BWK
Dated: January 20, 2006
Received: January 23, 2006

Dear Dr. McComb:

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,

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

Indications for Use

510(k) Number (if known): **K050123**

Device Name: **P-Stim System**

Indications For Use:

P-Stim is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K050123