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K062547

Attachment 2

MAR 2 1 2007

IV. 510(k) Summary

A. General Information on Submitter

Name: Gradient Technologies, LLC
Address: 6000 Poplar Ave Suite 400
Memphis, TN 38119
Telephone: 901-767-2384
Fax: 901-767-1782
Name of Contact Person: John Townsend

Date Summary Prepared: February 21, 2007

B. General Information on Device

Trade Name: Quadra Bloc TENS, Model 101

Classification Name: Transcutaneous electrical nerve stimulator, for pain relief

Product Code: GZJ

C. Predicate Device

Multi-Stim TENS, AP-101081T (K973979). Manufactured by Apex Medical Corp.

D. Description of the Device

The Quadra Bloc TENS, Model 101 is a battery powered portable TENS device. The Quadra Bloc TENS, Model 101 is a prescription device that is intended for use in relief of chronic intractable pain and adjunctive treatment of post-surgical or post-traumatic acute pain. The device is specifically designed to be small, portable and lightweight so as to not interfere with users movements and/or functions. The electronics unit consists of a housing that contains a battery compartment, display, entry keypad, electronic system, and output channels.

The Quadra Bloc TENS, Model 101 uses four AA alkaline batteries. The display is a single line 16-character alphanumeric display. The entry keypad is used for turning the device on/off, setting parameters on the device, and controlling operation. There are two output channels, designated Left and Right. They have a constant phase relation with each other but are independently set for amplitude. There is a separate two-wire cable for each channel. The electronics consists of a microprocessor (μP) to control and sequence all functions. It also reads the keyboard inputs. Output amplitude and display are under μP control. The electronics also boost the battery voltage to the level required for the stimulation pulse, as well as controls the timing for the pulse width and frequency.

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E. Intended Use

The Quadra Bloc TENS 101 is intended for use in relief of chronic intractable pain and adjunctive treatment of post-surgical or post-traumatic acute pain. This is a prescription device and should be used under continued medical supervision.

F. Technological Characteristics of Device Compared to Predicate Device

The technological characteristics of the proposed device are substantially equivalent to the identified predicate, Multi-Stim TENS manufactured by Apex Medical Corp. (K973979). The output specifications are the same except for minor differences in pulse width range, the number of output modes, net charge per pulse, power supply, maximum phase charge, and maximum power density which do not affect the safety or effectiveness of the device.

G. Recommended Electrodes

Brand Name	Model	Shape	Size	Surface Area	FDA 510(k) Number
Skylark	FI-4040	Round	2" X 2"	2026mm^2	K912643
UNI-PATCH	Easy Flex	Round	2" X 2"	2026mm^2	K961141
Axelgaard	Pals Plus	Round	2" X 2"	2026mm^2	K872976

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gradient Technologies, LLC
% Mr. Anthony T. Pavel, Jr.
K & L Gates
1601 K Street
Washington, DC 20006-1600

MAR 2 1 2007

Re: K062547
Trade/Device Name: Quadra Bloc TENS, Model 101
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator - Physical Medicine Devices
Regulatory Class: Class II
Product Code: GZJ
Dated: February 21, 2007
Received: February 22, 2007

Dear Mr. Pavel:

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 Paul Pinsky Deputy Director 3/21/07

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

Enclosure

V. Indications for Use Statement

Indications for Use

510(k) Number: K062547

Device Name: Quadra Bloc TENS Model 101

Indications for Use: Prescription

The Quadra Bloc TENS Model 101 is intended for use in relief of chronic intractable pain and adjunctive treatment of post-surgical or post-traumatic acute pain. This is a prescription device and should be used under continued medical supervision.

Prescription Use **Yes** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use **NO** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

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

510(k) Number K062547