K102278

**501(k) Summary**

OCT 2 0 2011

A. General Information on Submitter


Name: Gradient Technologies, LLC

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Memphis, TN 38119

Telephone: (901) 767-2384

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Name of Contact Person: John Townsend


Date Summary Prepared: February 21, 2007

B. General Information on Device

Trace Name: Quadra Bloc TENS, Model 101

Classification Name: Transcutaneous electrical nerve stimulator, for pan relief

Product Code: GZJ

C. Predicate Devices

i. The Quadra Bloc TENS, Model 101 –KO62547
ii. ComboCare 2000 – K083202
iii. Pepin Manufacturing Inc electrode - K070807

The current QuadraBloc TENS Model 101 is identical to the original QuadraBloc TENS Model 101; the modification to the QuadraBloc TENS Model 101 is identical to the PMI electrode. The ComboCare 2000 TENS and the QuadraBloc TENS Model 101 are substantially equivalent.

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 specially 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 (HP) to control and sequence all functions. It also reads the keyboard inputs. Output amplitude and display are under HP 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. The QuadraBloc TENS + Electrode, to be used in conjunction with the QuadraBloc TENS Model 101 is a PMI electrode with an attached QuadraBloc permanent magnet.

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-
   i. The QuadraBloc TENS Model 101 is identical to the device previously approved as KO62547.
   ii. The electrode is identical to the PMI electrode in composition - K070807
   iii. The permanent magnet is similar in characteristic to the ComboCare 2000 – K083202

| Brand Name | Model | Shape | Size | Surface Area | FDA Number |
|---|---|---|---|---|---|
| PMI | WF2 | Round | 2"x2" | 2026mm | K070807 |

V. Indications for Use Statement

510(k) Number: K102278/S1

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 adjunction treatment of post-surgical or post-traumatic acute pain. This is a prescription device and should be used under continued medical supervision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Gradient Technologies, LLC
c/o Mr. John Townsend,
President
6070 Poplar Avenue, Sixth Floor,
Memphis, TN 38119

OCT 2 0 2011

Re: K102278
Trade Name(s): Quadra Bloc TENS Model 101
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: October 17, 2011
Received: October 18, 2011

Dear Mr. Townsend:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keosia 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): K102278

Device Name: Quadra Bloc TENS Model 101

Indications For Use:

The QuadraBloc 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.
(Part 21 CFR 801 Sub part D)

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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



510(k) Number K102278