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K061799

AUG 28 2006

QuadraTENS Model QT-42
510(k) Summary Statement

1. This summary prepared by:

John C. Radke (contact person)
President/Official Correspondent

Revised on August 25, 2006

Submitted by BioResearch Associates, Inc.
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2. **QuadraTENS™ Model QT-42** (a two channel TENS device with four lead-wires)

Transcutaneous Electrical Neural Stimulator and Stimulator

Device: stimulator, nerve, transcutaneous, for pain relief
Regulation Description: Transcutaneous electrical nerve stimulator for pain relief

Regulation Medical Specialty: Neurology
Review Panels: Neurology
Product Codes: GZJ
Submission Type: 510(k) traditional
Regulation Number: 21 CFR 882.5890
Device Class: II
GMP exempt? [No]

3. Legally marketed equivalent devices

BioTENS™ 510(k) number = K844618B (TENS)
Empi Model 989 510(k) number = K881114 (burst mode feature)

4. The QuadraTENS Model QT-42 is a 2 channel version of the BioTENS with the addition of a burst mode. Like the BioTENS, it is also intended to be used by or on the order of a licensed practitioner. The burst mode has been added specifically because a single stimulus is sometimes insufficient. By adding a second channel, the QuadraTENS Model QT-42 can be applied simultaneously to another separately enervated area on the same patient.

✓ Dentist

The low frequency stimulation (1.0 Hz rate) of the QuadraTENS Model QT-42, the same as its predecessor BioTENS, is applied to a patient through surface electrodes.

The QuadraTENS Model QT-42 is designed and manufactured in compliance with FDA GMP regulations, ISO 9000 and ISO 13485 standards as well as RoHS. The Unit is powered by a single 9 volt battery. It produces a symmetrical bipolar pulse with a factory-set pulse-width of 600 microseconds and a rate of 1 pulse/second. The transformer-coupled outputs, which are equivalent to the both the BioTENS and the EMPI Model 989, apply 0.0 milliamps of net dc current to the patient.

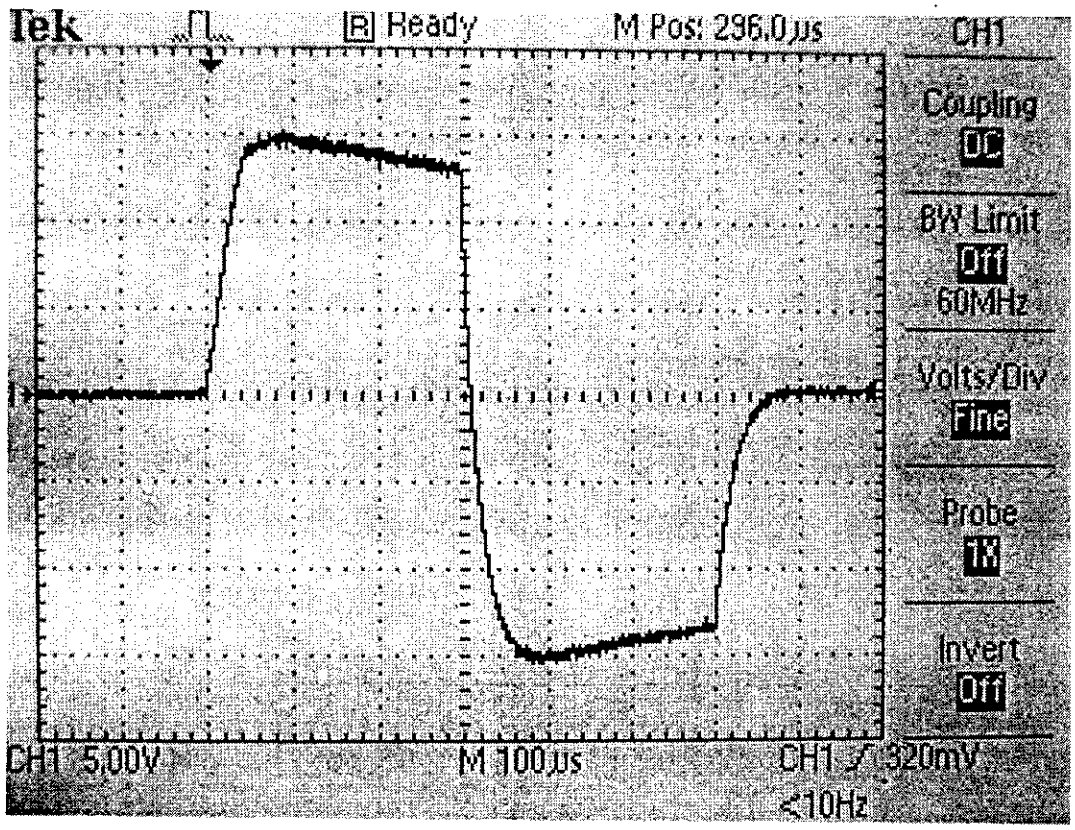

Fig. 1. Wave-shape and pulse-width of QuadraTENS Model QT-42 in single pulse mode applied across a 1,000 Ohm load (peak current shown = 15ma)

In the burst mode, a fixed train of 8 pulses with a repetition rate of 800 Hz is output once/second. The nominal pulse amplitude is controlled separately for each channel and ranges from 0.0 ma to a maximum of 40 milliamps peak. The 2 channels are isolated from each other and their output pulses are staggered in time to prevent any current from flowing between channels, which results in zero crosstalk. Each channel also includes a balance control that adjusts the amplitudes of the positive and negative half waves differentially. The balance is used to equalize the responses at each electrode site.

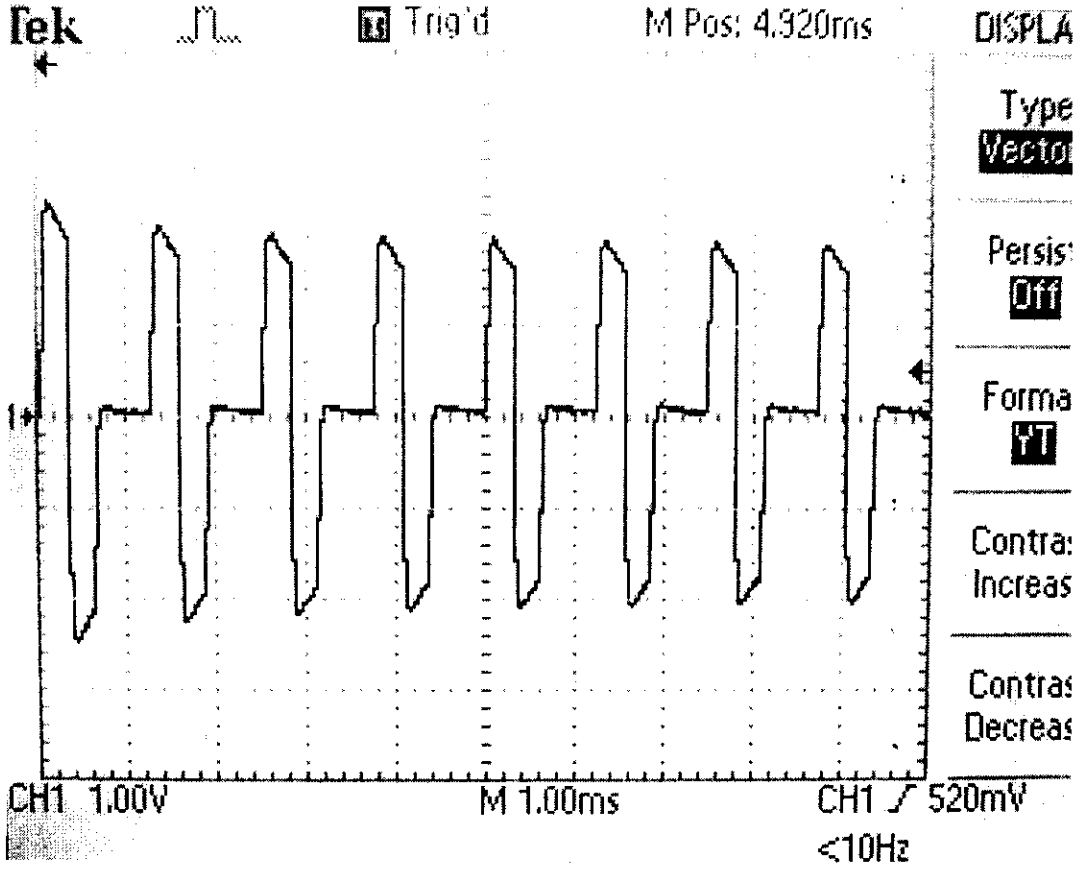

Fig. 2. Burst Mode Train of Eight Pulses. (Oscilloscope in 10X mode, 1,000 Ohm load, showing a peak current = 24 milliamps)

5. Intended use statement

The QuadraTENS Model QT-42 neuromuscular stimulator may be used for the symptomatic relief and management of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

6. Since the BioTENS has been functioning successfully for two decades and since we have received very few recommendations for changes, the QuadraTENS Model QT-42 has very few differences in its design. However, there have been changes in the technology of electronics in the past 20 years. Although both devices use digital logic to generate the frequency and pulse-width settings and analog controls for amplitude and balance, differences in construction include:

BioTENS	QuadraTENS Model QT-42
Through-hole PC Board and components	Surface-mount PC board and components
Hand assembled and soldered	Machine assembled and soldered
Permanently attached lead-wires	Detachable "touch-free" lead-wires
Custom-molded ABS case	Ready-made ABS case
FDA GMP Compliant	FDA GMP, ISO 9000/13485/RoHS compliant

In our opinion these differences should lead to greater reliability and fewer customer complaints.

Appendix 1

Assessment of performance (non-clinical)

Design qualification testing was performed for the following purposes:	Completed
1. Validation test of automatic stand-by mode for safety	[x]
2. Validation of symmetric bipolar waveform with zero net DC	[x]
3. Validation test of non-crossover between the separate channel outputs	[x]
4. Validation test of constant current outputs	[x]

The results of each test validate that the design meets all specifications, is equivalent to current legally marketed devices and is acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 28 2006

Bio-Research Associates
% Mr. John C. Radke
President
9275 North 49th Street, Suite 150
Brown Deer, Wisconsin 53223

Re: K061799
Trade Name: QuadraTENS, Model QT-42
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: August 11, 2006
Received: August 14, 2006

Dear Mr. Radke:

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,

Barbara Melkerson for

Mark N. Melkerson
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): K061799

Device Name: QuadraTENS Model QT-42

Indications For Use:

QuadraTENS is indicated for the symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-trauma acute pain.

Prescription Use X (Part 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 In Vitro Diagnostic Devices (OIVD)

Barbara Bachman for MXM

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K061799