K041092

510 (k) SUMMARY

JUL 01 2004

Statement:	This summary of 510(k) substantial equivalence is being submitted in accordance with the requirements of 21 CFR 807.92 and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.
Submitter's Identification:	Vision Quest Industries, Inc. 18011 Mitchell South Irvine, CA 92614 Contact Person: Jaime Pulley, VP of Quality Assurance/Regulatory Affairs Phone: (949) 794-3865 Fax: (949) 477-9672
Date Summary Prepared:	April 21, 2004
Name of Device:	Proprietary Name: Fast Start® TENS Common Name: (TENS) Transcutaneous Electrical Nerve Stimulator
Classification Name:	Stimulator, Nerve, Transcutaneous, for pain relief (GZJ)
Predicate Device Name:	Classic TENS™ 510(k) Number K020437 Mantra International Ltd. Room L-5 15/F Blk B, Vigor Industrial Building. 20 Cheung Tai Road Tsing Yi, Hong Kong

Device Description:

The Fast Start® TENS device is a transcutaneous electrical nerve stimulator that provides a non-invasive, drug free method of controlling acute and principally long term intractable pain. The device projects mild electrical impulses that are transmuted through the skin via surface electrodes to modify the body's pain perception. The FastStart ® TENS is made up of the device, one 9 V alkaline battery, a set of electrodes, two lead wires, and a carrying case.

Indications for Use

The TENS is used for symptomatic relief and management of chronic intractable pain,

and/or as an adjunctive treatment in the management of post surgical and post traumatic acute pain.

Comparison to Predicate

This device is similar to its predicate device, the Classic TENS, they both exhibit the same indications for use, technical characteristics and device specifications.

Conclusion

Designed with the same performance standards as its predicate, the Fast Start ® TENS does not raise any new questions in regards to safety and effectiveness. The device contains three modes of operation: Conventional, Burst, and Modulated. It is also equipped with twelve pre-set and two customized programs. The Fast Start TENS meets the mandatory performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 01 2004

Jaime X. Pulley
Vice President of Quality Assurance and Regulatory Affairs
VisionQuest Industries, Inc.
18011 Mitchell South
Irvine, California 92614

Re: K041092
Trade/Device Name: FastStart® TENS, Model FS 3001
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: April 21, 2004
Received: April 26, 2004

Dear Mr. Pulley:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041092

Device Name: Fast Start TENS

Indications For Use:

The TENS is used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post surgical and post traumatic acute pain

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

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