DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 - 2004

Ms. Cheryl Bagwell
Director of Regulatory Affairs
Chattanooga Group
A Division of Encore Medical
4717 Adams Road
P.O. Box 489
Hixson, Tennessee 37343-0489

Re: K031077

Trade Name: Vectra GENiSYS
Regulation Numbers: 21 CFR 890.5860, 882.5890, 890.5850, 882.5050, 882.5810
Regulation Names: Ultrasound and muscle stimulator, Transcutaneous electrical nerve stimulator for pain relief, Powered muscle stimulator, Biofeedback device, External functional neuromuscular stimulator
Regulatory Class: II
Product Codes: IMG, GZJ, IPF, HCC, GZI

Trade Name: Vectra GENiSYS
Regulation Number: Unclassified
Regulation Name: Interferential current therapy stimulator
Regulatory Class: II
Product Code: LIH

Dear Ms. Bagwell:

This letter corrects our substantially equivalent letter of December 11, 2003 regarding the Vectra GENiSYS Indications for use enclosure.

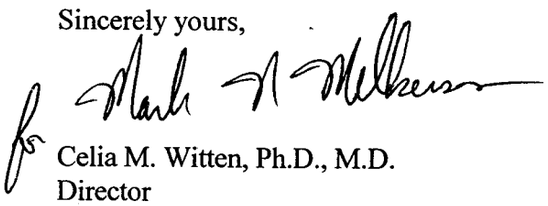
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



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

510(k) Number (if known): K031077

Device Name: Vectra GENiSYS (Intelect Legend XT)

Indications for Use: (Page 1 of 2)

For VMS, VMS Burst, Russian, Monophasic Hi-Volt (NMES) & Interferential and Premodulated (IFS)

Relaxation of Muscle Spasms
Prevention or retardation of disuse atrophy
Increasing local blood circulation
Muscle re-education
Maintaining or increasing range of motion
Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

Additionally for Microcurrent, Interferential, Premodulated (IFS), VMS, VMS Burst, Asymmetrical Biphasic (TENS) and Symmetrical Biphasic (TENS)

Symptomatic relief or management of chronic, intractable pain
Post-traumatic acute pain
Post-surgical acute pain

For FES

Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait

For DC Continuous Mode

Relaxation of muscle spasm

For EMG

To determination the activation timing of muscles for: a) retraining of muscle activation b) coordination of muscle activation
An indication of the force produced by muscle for control and maintenance of muscle contractions
Relaxation muscle training
Muscle re-education

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

510(k) Number K031077

(Optional Format 1-2-96)

510(k) Number (if known): K031077

Device Name: Vectra GENiSYS (Intelect Legend XT)

Indications for Use: (Page 2 of 2)

For EMG triggered Stim

Stroke rehab by muscle re-education
Relaxation of muscle spasms
Prevention or retardation of disuse atrophy
Increase local blood circulation
Muscle re-education
Maintaining or increasing range of motion

For Ultrasound

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:
1. Relief of pain, muscle spasms and joint contractures
2. Relief of pain, muscle spasms and joint contractures that may be associated with:
a) Adhesive capsulitis
b) Bursitis with slight calcification
c) Myositis
d) Soft tissue injuries
e) Shortened tendons due to past injuries and scar tissues
3. Relief of sub-chronic and chronic pain and joint contractures resulting from:
a) Capsular tightness
b) Capsular scarring

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)

Division of General, Restorative, and Neurological Devices

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

510(k) Number K031077

(Optional Format 1-2-96)