510(k) Notification: VT-200

May 24, 2012

510(k): k121662

510(k) SUMMARY

Submitter Information:

Alan Neuromedical Technologies
6001 B South Staples
Corpus Christi, TX 78413
361-992-9432

NOV 21 2012

Regulatory Affairs Contact:

Amy Pieper
Regulatory Affairs Consultant
(512) 657-9340 -- phone
piepers@austin.rr.com -- email

Date Summary Prepared:

March 1, 2012

Device Identification:

Trade Name:	VT-200
Common Name:	Interferential Current Therapy Device
Classification Name:	Interferential Current Therapy (LIH)

Predicate Device:

Dynatron STS (k010565)

Intended Use:

Electrical stimulation delivered by the device is intended for the symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain.

Functional Description and Technological Characteristics:

The VT-200, or VECTTOR system, delivers electrical stimulation via electrodes on acupressure points of a patient's feet/legs and hands/arms to provide symptomatic relief of chronic intractable pain and/or management of post-surgical pain. Once these electrodes are placed, the machine determines the appropriate stimulation intensity by automatically measuring body temperatures through the use of two specially designed Thermistors placed on the fingers during a testing sequence. The VT-200 delivers four channels of current from dual output jacks through Treatment Leads and Electrodes which are positioned on the patient's body according to treatment protocols.

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Substantial Equivalence:

The VT-200 and the Dynatron STS have the same intended use and functional characteristics. The VT-200 takes some of the manual portions of the Dynatron STS and automates them using software. In summary, the VT-200 is functionally equivalent to the Dynatron STS and therefore, substantially equivalent.

Performance Testing:

Performance testing of the VT-200 has been conducted for functional and design verification and validation. The testing indicates the device is in compliance with the following recognized consensus standards:

- IEC 60601-1 Medical Electrical Equipment, Part 1 : General Requirements for Safety
- IEC 60601-1-2 Medical Electrical Equipment, Part 1: General Requirements for Safety, Electromagnetic Compatibility-Requirements and Tests

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 21, 2012

Alan Neuromedical Technologies
% Dr. Donald A. Rhodes
President
6001-B S. Staples Street
Corpus Christi, TX 78413

Re: K121662
Trade/Device Name: VECTTOR VT-200
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LIH
Dated: August 28, 2012
Received: September 26, 2012

Dear Dr. Rhodes:

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

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,

Kesia Y. Alexander

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): K121662

Device Name: VT-200 (Interferential Current Therapy Device)

Indications For Use:

Electrical stimulation delivered by the device is intended for the symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical 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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Neurological and Physical Medicine Devices
510(k) Number K121662