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Appendix 13
510(k) Summary of Safety and Effectiveness

Vertis Neuroscience, Inc.
Percutaneous Neuromodulation Therapy (PNT) ™ Control Unit and Accessories

General Information

Classification	Class II
Trade Name	Percutaneous Neuromodulation Therapy (PNT) Nerve Stimulation System
Submitter	Vertis Neuroscience, Inc. 2101 Fourth Avenue, Suite 200 Seattle, Washington, USA 98121
Contact	Lori Glastetter Vice President, Regulatory Affairs/ Quality Assurance

Nature of this 510(k)

The Vertis Percutaneous Neuromodulation Therapy (PNT) System (nerve stimulator and accessories) was cleared for marketing under 510(k) Notification K011702. This submission was filed to request clearance to market a new cervical electrode kit and cable and modify the existing PNT labeling to accommodate these new accessories.

Device Description

The Vertis PNT System is designed for delivering percutaneous electrical stimulation (termed: Percutaneous Neuromodulation Therapy - PNT). The Vertis PNT System is intended to be used in pain management by a physician (e.g., anesthesiologists or physical medicine and rehabilitation physicians) or on the order of a physician (e.g., by a physical therapist) in a clinic environment. The device system includes 3 major components:

- the *Vertis PNT Control Unit* - a software-driven, five channel, AC powered nerve stimulator which generates the electrical stimulus;
- the sterile *Safeguides* – which are sterile, needle electrodes;
- the *Patient Cable* - which interconnects the PNT Control Unit to the electrodes

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Indications for use

Percutaneous Neuromodulation Therapy (PNT) is indicated for the symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment in the management of post-surgical pain and post-trauma pain.

The PNT Control Unit is to be used with PNT Lumbar Safeguides for low back pain or PNT Cervical Safeguides for neck and/or upper back pain.

Substantially Equivalent Devices

Manufacturer	*Substantially Equivalent devices*	*510(k)*
Vertis Neuroscience, Inc.	Vertis Percutaneous Neuromodulation Therapy (PNT) Stimulation System (Vertis PNT Control Unit and Accessories) Model CU 100 and SG 101-xxx	K011702
Empi, Inc. St. Paul, MN	EPIX Tens Device System Model EPIX VT Model EPIX XL	K970203 K951903
Rehabilicare, Inc. New Brighton, MN	SMP-Plus™ Model 4930	K982410

Safety and Effectiveness - Testing

Extensive data were provided that evaluated the use of PNT cervical electrodes and cervical percutaneous electrical stimulation. These data included the following. Data demonstrated acceptable results for the device and therapy.

- electrode performance and dimensional (bench) data
- human magnetic resonance images (MRI)/ computerized tomography (CT) imaging data
- published human clinical trial data for cervical pain management
- post-market data for the Vertis PNT System

Summary of Substantial Equivalence

Based on the information provided in this Notification, we believe the described modification to the legally marketed predicate Vertis PNT™ Control Unit and Accessories has been shown to be substantially equivalent to devices in commercial distribution prior to May 28, 1976.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2002

Lori J. Glastetter
Vice President, Regulatory Affairs/Quality Assurance
Vertis Neuroscience, Inc.
2101 Fourth Avenue, Suite 200
Seattle, Washington 98121

Re: K022241
Trade/Device Name: Vertis Percutaneous Neuromodulation Therapy (PNT) Nerve Stimulation System (Vertis PNT Control Unit, Vertis PNT Lumbar Safeguides and Vertis PNT Cervical Safeguides)
Regulation Number: 21 CFR 882.5890 and 21 CFR 882.1350
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief and Needle Electrode
Regulatory Class: Class II
Product Code: NHI and GXZ
Dated: July 10, 2002
Received: July 11, 2002

Dear Ms. Glastetter:

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.

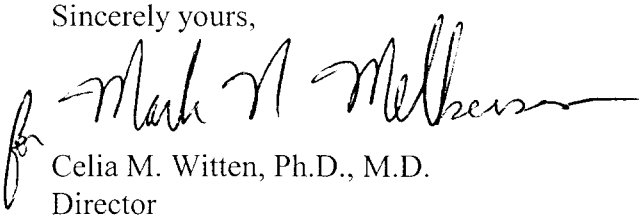
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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): K 022241

Device Name:_____

Indications For Use:

Percutaneous Neuromodulation Therapy (PNT) is indicated for the symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment in the management of post-surgical pain and post-trauma pain.

The PNT Control Unit is to be used with PNT Lumbar Safeguides for low back pain or PNT Cervical Safeguides for neck and/or upper back pain.

(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)

(Optional Format 3-10-98)

for Mark N Milhous

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

510(k) Number K022241