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neurovision MEDICAL

Traditional 510k – EMGView Software

DEC 21 2010

510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807 and in particular 21 CFR §807.92, the following summary of information is provided:

Date: 12/10/10

Submitter: Christine Vergely
Neurovision Medical Products, Inc.
2225 Sperry Ave., Suite 1000
Ventura, CA 93003
Telephone: (866) 815-6999
Fax: (314) 310-4579

Trade or Proprietary Name:	EMGView Software
Common or Usual Name:	EMG software for Windows® PC
Classification Name:	Surgical nerve stimulator/locator (21 CFR §874.1820)
Predicate Device:	Neurovision Nerve Locator/Monitor (K954601)

Device Description:

The EMGView Software is a Windows PC operating system software dedicated to viewing and documentation of the output of the Neurovision (Nerveäna) Nerve Locator/Monitor. The software is dedicated to the EMG device by a serial USB connection. The EMGView software is a read-only device and is thus incapable of modifying or controlling the Nerveäna Device.

Intended Use:

The EMGView software is an accessory to the Neurovision Nerve Locator/Monitor. When the dedicated USB output of the EMG unit is connected to a personal computer, the PC installed software provides status monitoring data, troubleshooting data, real-time EMG waveforms, and digital backup of all data obtained during clinical use of the device.

Indications for Use:

The Neurovision Nerve Locator/Monitor is an electronic device consisting of a surgical nerve stimulator and an evoked EMG monitor with integrated detecting and warning capability. This device is intended for use in surgical procedures where motor nerves are at risk to assist the surgeon in locating these nerves. This device is intended for

use only by qualified, trained medical practioners who perform operative surgery and who fully understand that this device is only an adjuvant to proper surgical technique and good surgical judgment.

The EMGView software is an accessory to the Neurovision Nerve Locator/Monitor. When the dedicated USB output of the EMG unit is connected to a personal computer, the PC installed software provides status monitoring data, troubleshooting data, real-time EMG waveforms, and digital backup of all data obtained during clinical use of the device. The real-time display of EMG waveforms is intended to assist the surgeon with nerve integrity monitoring.

Technological Characteristics:

The EMGView software is a PC installed software accessory to the Neurovision Nerve Locator/Monitor.

	Subject Device	**Predicate device (after approved modification**
	Neurovision (Nerveäna) with *EMGView Software*	Nerveäna (post 2006) K954601
Surgical Nerve Locator/Monitor	Yes	Yes
Device data output	Dedicated serial USB to PC	Dedicated serial USB to PC
Indications for Use	The Neurovision Nerve Locator/Monitor is an electronic device consisting of a surgical nerve stimulator and an evoked EMG monitor with integrated detecting and warning capability. This device is intended for use in surgical procedures where motor nerves are at risk to assist the surgeon in locating these nerves. This device is intended for use only by qualified, trained medical practioners who perform operative surgery and who fully understand that this device is only an adjuvant to proper surgical technique and good surgical judgment. The EMGView software is an accessory to the Neurovision Nerve Locator/Monitor. When the dedicated USB output of the EMG unit is connected to a personal computer, the PC	The Neurovision Nerve Locator/Monitor is an electronic device consisting of a surgical nerve stimulator and an evoked EMG monitor with integrated detecting and warning capability. This device is intended for use in surgical procedures where motor nerves are at risk to assist the surgeon in locating these nerves. This device is intended for use only by qualified, trained medical practioners who perform operative surgery and who fully understand that this device is only an adjuvant to proper surgical technique and good surgical judgment.

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Software	Dedicated *EMGView Program*	N/A
EMG Waveform Display	PC Based Accessory	N/A
PC based threshold audio alarm	PC Based Accessory	N/A
Database and Playback capability	PC Based Accessory	N/A

Safety and Efficacy

The EMGView Software (v4.31, current version) requirements were verified using the Nerveana bench testing performance as a baseline. The software was validated by confirming that its clinical use conforms to user needs.

The Nerveäna device with EMGView software is as safe and effective as the Nerveäna device alone in locating and monitoring motor nerves during surgery:

- The EMGView software, being a read-only device accessory, does not affect the performance of the Nerveäna device.
- No surgeon input is required for operation of the Nerveäna accessory.
- The EMGView software provides additional troubleshooting tools for the surgeon to verify proper Nerveäna operation and electrode position.
- The Database Feature of the Nerveäna provides focus by the surgeon on the issue of proper nerve location and preservation as well as providing postoperative review data that would otherwise be unobtainable in answering any questions about the relationship of nerve monitoring to the surgical outcome.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neurovision Medical Products, Inc.
c/o Ms. Christine Vergely
Regulatory Manager
2225 Sperry Avenue, Suite 1000
Ventura, CA 93003

DEC 2 1 2010

Re: K102862
Trade/Device Name: EMGView Software (v4.31)
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN
Dated: December 10, 2010
Received: December 13, 2010

Dear Ms. Vergely:

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 device-related adverse events) (21 CFR 803); 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.

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102862

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K102862