



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

April 5, 2017

Neurovision Medical Product Inc.  
Christine Vergély  
Director of Quality and Regulatory  
353 San Jon Rd  
Ventura, California 93001

Re: K170677

Trade/Device Name: Neurovision Nerve Locator Monitor (Nerveana) and EMGView  
Software

Regulation Number: 21 CFR 882.1870

Regulation Name: Evoked Response Electrical Stimulator

Regulatory Class: Class II

Product Codes: GWF, ETN

Dated: February 8, 2017

Received: March 6, 2017

Dear Ms. Vergély:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

**Michael J. Hoffmann -S**

for Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K170677

Device Name  
Neurovision Nerve Locator Monitor (Nerveana) and EMGView Software

### Indications for Use (Describe)

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 practitioners 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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