K132694

**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:

**A. Submitted by:**

Sheila Bruschi
Manager, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800
Date Prepared: May 13, 2014

**B. Device Name**

| | |
|---|---|
| Trade or Proprietary Name: | *NuVasive® NVM5® System* |
| Common or Usual Name: | Neurological surgical monitor;<br>Stereotaxic Instrument |
| Classification Name: | Neuro Surgical Nerve Stimulator/Locator;<br>Evoked response electrical stimulator;<br>Neurological stereotaxic instrument;<br>Electromyography (EMG) monitor/stimulator |
| Device Class: | Class II |
| Classification: | §874.1820, §882.1870, §882.4560, §890.1375 |
| Product Code: | PDQ, ETN, GWF, HAW, IKN, OLO |

**C. Predicate Devices**

The subject *NuVasive NVM5 System* is substantially equivalent to the predicates:

- 510(k) K123307, NuVasive NVM5 System
- 510(k) K991054, Nicolet Biomedical, Inc. Bravo Multi-Modality System
- 510(k) K092744, R&D Medical Products, Inc. Neonatal ECG Electrodes

**D. Device Description**

The *NVM5 System* is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. *NVM5* provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), motor evoked potential (MEP) or somatosensory evoked potential (SSEP) responses of nerves. Moreover, a Twitch Test function is utilized to test the ability of the nerve to respond, or contract, following four stimulation pulses to determine the presence of neuromuscular block.

Additionally, the *NVM5 System* includes an integrated stereotactic guidance system (*NVM5 Guidance*) to support the delivery of pedicle screws during EMG monitoring. The System also

integrates Bendini® software used to locate spinal implant instrumentation for the placement of spinal rods. Lastly, the system also offers an optional screen sharing application to allow a secondary physician to remotely view the events represented on the NVM5 user interface. In summary, the *NVM5 System* includes the following six (6) software functionalities / modalities:

1. Electromyography (EMG)
2. Motor Evoked Potential (MEP)
3. Somatosensory Evoked Potential (SSEP)
4. Remote Reader
5. Guidance
6. Bendini

The *NVM5 System* hardware consists of a Patient Module (PM) and computer, as well as accompanying accessory components which consist of an assortment of disposable conductive probes, electrodes, and electrode leads.

## E. Intended Use

The *NVM5 System* is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. *NVM5* provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), transcranial or lumbar motor evoked potential (MEP), or somatosensory evoked potential (SSEP) responses of nerves. The System also integrates Bendini® software used to locate spinal implant instrumentation for the placement of spinal rods.

- XLIF (Detection) – The XLIF (Detection) function allows the surgeon to locate and evaluate spinal nerves, and is used as a nerve avoidance tool.
- Basic & Dynamic Screw Test – The Screw Test functions allow the surgeon to locate and evaluate spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws.
- Free Run EMG – The Free Run EMG function identifies spontaneous EMG activity of spinal nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions.
- Twitch Test (Train of Four) – The Twitch Test Function allows the surgeon to assess moderate degrees of neuromuscular block in effect by evaluating muscle contraction following a train of four stimulation pulses.
- MEP – Transcranial or lumbar (i.e., conus in region of L1-L2) stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract and peripheral nerves. The MEP function provides an adjunctive method to allow the surgeon to monitor spinal cord and motor pathway integrity during procedures with a risk of surgically induced motor injury.
- SSEP – The SSEP function allows the surgeon to assess sensory spinal cord function in surgical procedures during which the spinal cord is at risk.

- Remote Reader – The Remote Reader function provides real time remote access to the NVM5 System for a monitoring physician outside of the operating room.
- Guidance – The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation procedures in the lumbar and sacral spine (L1-S1) of adult patients, and when used in conjunction with radiographic imaging and EMG, allows the surgeon to assess the angulation of system accessories relative to patient spinal anatomy for the creation of a cannulation trajectory for bone screw placement.
- Bendini – The Bendini Spinal Rod Bending function is used to locate spinal implant system instrumentation (screws, hooks) to determine their relative location to one another to generate bend instructions to shape a spinal rod. A surgeon is able to use those instructions and bend a rod using the Bendini Bender, a mechanical rod bender.

## F. Technological Characteristics

As was established in this submission, the subject *NVM5 System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and functions. The technological differences within this 510(k) that were shown to be substantially equivalent to the predicates include:

- Additional Dual Surface Electrodes
- Modified MEP Indications for Use
- Modified SSEP specifications

## Table 1 – Comparison of Technical Characteristics

| Specification/ Property | Predicate Device<br>NuVasive NVM5 System (K123307) | Subject Device<br>NuVasive NVM5 System |
|---|---|---|
| Intended Use / Indications for Use | The *NVM5® System* is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. *NVM5* provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), transcranial motor evoked potential (TceMEP) or somatosensory evoked potential (SSEP) responses of nerves. The System also integrates Bendini™ software used to locate spinal implant instrumentation for the placement of spinal rods.<br>• XLIF (Detection) – The XLIF (Detection) function allows the surgeon to locate and evaluate spinal nerves, and is used as a nerve avoidance tool.<br>• Basic & Dynamic Screw Test – The Screw Test functions allow the surgeon to locate and evaluate spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws.<br>• Free Run EMG – The Free Run EMG function identifies spontaneous EMG activity of spinal nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions.<br>• Twitch Test (Train of Four) – The Twitch Test Function allows the surgeon to assess moderate degrees of neuromuscular block in effect by evaluating muscle contraction following a train of four stimulation pulses.<br>• TceMEP – Transcranial stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract. The TceMEP function provides an adjunctive method to allow the surgeon to monitor spinal cord and motor pathway integrity during procedures with a risk of surgically induced motor injury.<br>• SSEP – The SSEP function allows the surgeon to assess sensory spinal cord function in surgical procedures during which the spinal cord is at risk.<br>• Remote Reader – The Remote Reader function provides real time remote access to the NVM5 System for a monitoring physician outside of the operating room.<br>• Guidance – The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation procedures in the lumbar and sacral spine (L1-S1) of adult patients, and when used in conjunction with radiographic imaging and EMG, allows the surgeon to assess the angulation of system accessories relative to patient spinal anatomy for the creation of a cannulation trajectory for bone screw placement.<br>• Bendini – The Bendini Spinal Rod Bending function is used to locate spinal implant system instrumentation (screws, hooks) to determine their relative location to one another to generate bend instructions to shape a spinal rod. A surgeon is able to use those instructions and bend a rod using the Bendini Bender, a mechanical rod bender. | The *NVM5® System* is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. *NVM5* provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), transcranial or lumbar motor evoked potential (MEP), or somatosensory evoked potential (SSEP) responses of nerves. The System also integrates Bendini® software used to locate spinal implant instrumentation for the placement of spinal rods.<br>• XLIF (Detection) – The XLIF (Detection) function allows the surgeon to locate and evaluate spinal nerves, and is used as a nerve avoidance tool.<br>• Basic & Dynamic Screw Test – The Screw Test functions allow the surgeon to locate and evaluate spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws.<br>• Free Run EMG – The Free Run EMG function identifies spontaneous EMG activity of spinal nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions.<br>• Twitch Test (Train of Four) – The Twitch Test Function allows the surgeon to assess moderate degrees of neuromuscular block in effect by evaluating muscle contraction following a train of four stimulation pulses.<br>• MEP – Transcranial or lumbar (i.e., conus in region of L1-L2) stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract and peripheral nerves. The MEP function provides an adjunctive method to allow the surgeon to monitor spinal cord and motor pathway integrity during procedures with a risk of surgically induced motor injury.<br>• SSEP – The SSEP function allows the surgeon to assess sensory spinal cord function in surgical procedures during which the spinal cord is at risk.<br>• Remote Reader – The Remote Reader function provides real time remote access to the NVM5 System for a monitoring physician outside of the operating room.<br>• Guidance – The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation procedures in the thoracolumbar and sacral spine (T8-S1) of adult patients, and when used in conjunction with radiographic imaging and EMG, allows the surgeon to assess the angulation of system accessories relative to patient spinal anatomy for the creation of a cannulation trajectory for bone screw placement.<br>• Bendini – The Bendini Spinal Rod Bending function is used to locate spinal implant system instrumentation (screws, hooks) to determine their relative location to one another to generate bend instructions to shape a spinal rod. A surgeon is able to use those instructions and bend a rod using the Bendini Bender, a mechanical rod bender. |

| Specification/ Property | Predicate Device<br>NuVasive NVM5 System (K123307) | Subject Device<br>NuVasive NVM5 System |
|---|---|---|
| Software Modalities / Functionalities | • XLIF (Detection)<br>• Basic & Dynamic Screw Test<br>• Free Run EMG<br>• Twitch Test<br>• TceMEP<br>• SSEP<br>• Remote Monitoring<br>• Guidance<br>• Bendini | • XLIF (Detection)<br>• Basic & Dynamic Screw Test<br>• Free Run EMG<br>• Twitch Test<br>• MEP<br>• SSEP<br>• Remote Monitoring<br>• Guidance<br>• Bendini |
| Algorithms | • XLIF (Detection)<br>• Basic & Dynamic Screw Test<br>• Free Run EMG<br>• Twitch Test<br>• TceMEP<br>• SSEP<br>• Guidance<br>• Bendini | Identical algorithms as predicate. |
| Total Available Channels | 32 | 32 |
| Headbox/ Patient Module | Yes | Yes |
| IEC 60601-1 Compliant | Yes | Yes |
| Full Scale View Range | ± 0.5µV to ± 8mV | ± 0.5µV to ± 8mV |
| Frequency Response | 3 Hz to 4.8 kHz | 3 Hz to 4.8 kHz |
| User Interface | NuVasive-supplied computer or<br>NuVasive provided touch screen and [optional] keyboard/mouse | NuVasive-supplied computer or<br>NuVasive provided touch screen and [optional] keyboard/mouse |
| Remote Monitoring | Yes | Yes |
| Train of Four Testing | Yes | Yes |
| Needle Electrodes | Various | Various |
| Surface Electrodes | Various | Various |

| Specification/ Property | Predicate Device<br>NuVasive NVM5 System (K123307) | Subject Device<br>NuVasive NVM5 System |
|---|---|---|
| Electrode Leads | Various | Various |
| Stimulating Probes | Various | Various |
| Recording Channels | EMG, MEP, and SSEP | EMG, MEP, and SSEP |
| **EMG** | | |
| EMG Modalities | • XLIF (Detection)<br>• Basic & Dynamic Screw Test<br>• Free Run EMG<br>• Twitch Test | • XLIF (Detection)<br>• Basic & Dynamic Screw Test<br>• Free Run EMG<br>• Twitch Test |
| **XLIF (Detection)** | | |
| Types of Modes | Automatic Stimulation | Automatic Stimulation |
| Threshold Values for Color Alerts | Yes | Yes (Identical to predicate) |
| Audio feedback | Yes | Yes |
| **Basic & Dynamic Screw Test** | | |
| Types of Modes | Automatic Stimulation | Automatic Stimulation |
| Threshold Values for Color Alerts | Yes | Yes (Identical to predicate) |
| Audio feedback | Yes | Yes |
| **Free Run EMG** | | |
| Types of Modes | Manual Stimulation | Manual Stimulation |
| Threshold Values for Color Alert | Yes | Yes (Identical to predicate) |
| Audio feedback | Yes | Yes |
| **Twitch Test** | | |
| Types of Modes | Manual and Automatic Stimulation | Manual and Automatic Stimulation |
| Threshold Values for Color Alerts | Yes | Yes (Identical to predicate) |
| Audio feedback | Yes | Yes |
| **MEP** | | |
| Types of Modes | Manual and Automatic Stimulation | Manual and Automatic Stimulation |
| Threshold Values for Color Alerts | Yes | Yes (Identical to predicate) |
| Audio feedback | Yes | Yes |
| **SSEP** | | |
| Types of Modes | Manual Stimulation | Manual Stimulation |

| Specification/ Property | Predicate Device NuVasive NVM5 System (K123307) | Subject Device NuVasive NVM5 System |
|---|---|---|
| Threshold Values for Color Alerts | Yes | Yes |
| Audio feedback | Yes | Yes |
| **Remote Access** | | |
| Screen-sharing accessibility | Remote Monitoring | Remote Monitoring |
| **Guidance** | | |
| Clinical Use | • Requires input derived from CT, MRI, or radiographic images<br>• Intended to assist the surgeon in cannulating the pedicle based on user predefined trajectory<br>• Integrated with EMG stimulation | • Requires input derived from CT, MRI, or radiographic images<br>• Intended to assist the surgeon in cannulating the pedicle based on user predefined trajectory<br>• Integrated with EMG stimulation |
| Performance Requirements | • Angular tolerance of ±2°<br>• Confirmation of alignment to pre-planned trajectory<br>• Seamlessly integrated with an insulated Jamshidi Needle | • Angular tolerance of ±2°<br>• Confirmation of alignment to pre-planned trajectory<br>• Seamlessly integrated with an insulated Jamshidi Needle |
| IEC 60601 Compliant | YES | YES |
| User Interface | Touch screen, graphical user interface and audio | Touch screen, graphical user interface and audio |
| **Bendini** | | |
| Components | Optical (IR) tracking technology system, IR tracking instruments, computer. | Optical (IR) tracking technology system, IR tracking instruments, computer. |
| User Interface | Touch screen, graphical user interface and audio. | Touch screen, graphical user interface and audio. |
| IEC 60601 Compliant | YES | YES |
| Instrumentation | • IR Digitizer (with integrated passive spheres)<br>• Rod Bender | • IR Digitizer (with integrated passive spheres)<br>• Rod Bender |

## G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *NVM5 System* is substantially equivalent to other predicate devices and to verify that the *NVM5 System* meets design specifications and performance characteristics, based upon the intended use. The *NVM5 System* was subjected to verification and validation testing, as follows:

- NVM5 System Verification and Validation Testing according to the Software Requirements Specifications defined for the system, to include the modifications made as part of the subject device
- NVM5 System software Regression Testing
- Bendini System Integration Testing
- Dual Surface Electrode Functional Testing
- ISO 10993 Biocompatibility Testing – cytotoxicity, sensitization, and irritation/intracutaneous

The results of these studies showed that the subject *NVM5® System* meets or exceeds the performance of the predicate device, and the device was therefore found to be substantially equivalent.

## H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *NVM5 System* has been shown to be substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 16, 2014

NuVasive, Inc.
Ms. Sheila Bruschi
Manager, Regulatory Affairs
7475 Lusk Blvd.
San Diego, CA 92121

Re: K132694
Trade/Device Name: NuVasive NVM5 System
Regulation Number: 21 CFR 874.1820
Regulation Name: Neurosurgical nerve locator
Regulatory Class: Class II
Product Code: PDQ, ETN, GWF, HAW, IKN, OLO
Dated: April 17, 2014
Received: April 18, 2014

Dear Ms. Bruschi:

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 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. 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,

Carlos L. Peña -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K132694

Device Name
NuVasive® NVM5 System

Indications for Use *(Describe)*
The NVM5® System is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. NVM5 provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), transcranial or lumbar motor evoked potential (MEP), or somatosensory evoked potential (SSEP) responses of nerves. The System also integrates Bendini® software used to locate spinal implant instrumentation for the placement of spinal rods.

- XLIF (Detection) – The XLIF (Detection) function allows the surgeon to locate and evaluate spinal nerves, and is used as a nerve avoidance tool.
- Basic & Dynamic Screw Test – The Screw Test functions allow the surgeon to locate and evaluate spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws.
- Free Run EMG – The Free Run EMG function identifies spontaneous EMG activity of spinal nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions.
- Twitch Test (Train of Four) – The Twitch Test Function allows the surgeon to assess moderate degrees of neuromuscular block in effect by evaluating muscle contraction following a train of four stimulation pulses.
- MEP – Transcranial or lumbar (i.e., conus in region of L1-L2) stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract and peripheral nerves. The MEP function provides an adjunctive method to allow the surgeon to monitor spinal cord and motor pathway integrity during procedures with a risk of surgically induced motor injury.
- SSEP – The SSEP function allows the surgeon to assess sensory spinal cord function in surgical procedures during which the spinal cord is at risk.
- Remote Reader – The Remote Reader function provides real time remote access to the NVM5 System for a monitoring physician outside of the operating room.
- Guidance – The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation procedures in the lumbar and sacral spine (L1-S1) of adult patients, and when used in conjunction with radiographic imaging and EMG, allows the surgeon to assess the angulation of system accessories relative to patient spinal anatomy for the creation of a cannulation trajectory for bone screw placement.
- Bendini – The Bendini Spinal Rod Bending function is used to locate spinal implant system instrumentation (screws, hooks) to determine their relative location to one another to generate bend instructions to shape a spinal rod. A surgeon is able to use those instructions and bend a rod using the Bendini Bender, a mechanical rod bender.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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*PRAStaff@fda.hhs.gov*

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