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
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7475 Lusk Blvd.
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Date Prepared: March 13, 2013

B. Device Name

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

C. Predicate Devices

The subject *NuVasive NVM5 System* is substantially equivalent to one or more of the following predicate devices listed in Table 1 below.

Table 1 – Predicate Devices

510(k)	Trade or proprietary or model name	Manufacturer
K112718	NVM5 System	NuVasive, Inc.
K122742	Bendini™ Spinal Rod Bending System	NuVasive, Inc.
K050438	StealthStation	Medtronic
K012448	VectorVision Trauma	BrainLAB

D. Device Description

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 (TcMEP) or somatosensory evoked potential (SSEP) responses of nerves. Moreover, a Twitch Test ("Train of Four") 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 (*Remote Monitoring*) 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. Transcranial Motor Evoked Potential (TceMEP), or simply MEP
3. Somatosensory Evoked Potential (SSEP)
4. Guidance
5. Bendini
6. Remote Monitoring

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 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.

- 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.
- 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.
- 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:

- Addition of Red/Yellow/Green background alerts to the SSEP Function
- Addition of the Bendini function (equivalent to predicate Bendini System K122742), and
- Use of the *NVM5 System* with NuVasive-supplied compatible computer.

Table 2 – Comparison of Characteristics of the Subject NVM5 System vs. Predicate Device

Specification/ Property	Subject Device NuVasive NVM5 System	Predicate Device NuVasive NVM5 System (K112718)	Substantially Equivalent?
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. • 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. • 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. • 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.	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 (TcMEP) or somatosensory evoked potential (SSEP) responses of nerves. • 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. • TcMEP – Transcranial stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract. The TcMEP function provides an adjunctive method to allow the surgeon to monitor spinal cord 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. • The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation procedures in the lumbar spine 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.	YES. The differences in the Indications do not result in a new intended use and do not alter the intended therapeutic effect or impact safety/ effectiveness as the Bendini indications are identical to those cleared in K122742; and Guidance indications were only expanded to include the S1 level of the spine.

Specification/ Property	Subject Device NuVasive NVM5 System	Predicate Device NuVasive NVM5 System (K112718)	Substantially Equivalent?
Software Functionalities/ Modalities	• XLIF Detection • Basic & Dynamic Screw Test • Free Run EMG • Twitch Test (Train of Four) • TceMEP • SSEP • Remote Monitoring • Guidance • Bendini	• XLIF Detection • Basic & Dynamic Screw Test • Free Run EMG • Twitch Test (Train of Four) • TceMEP • SSEP • Remote Monitoring • Guidance	Yes. Bendini function was cleared in 510(k) K122742, and verification testing demonstrated use with the NVM5 System.
Algorithms	Identical algorithms as predicate, with additional algorithms for SSEP Auto and Bendini functions	• XLIF Detection • Basic & Dynamic Screw Test • Free Run EMG • Twitch Test (Train of Four) • TceMEP • SSEP • Guidance	Yes. Bendini algorithm is substantially equivalent to predicate 510(k) K122742.
Total Available Channels	32	32	Yes
Headbox/ Patient Module	Yes	Yes	Yes
IEC 60601-1 Compliant	Yes	Yes	Yes
Full Scale View Range	± 0.5µV to ± 8mV	± 0.5µV to ± 8mV	Yes
Frequency Response	3 Hz to 4.8 kHz	3 Hz to 4.8 kHz	Yes
User Interface	NuVasive-supplied computer with optional touch screen and/or keyboard/mouse	Control Unit: Touch screen and [optional] keyboard/mouse	Yes
Remote Monitoring	Yes	Yes	Yes
Train of Four Testing	Yes	Yes	Yes
Needle Electrodes	Various (Identical to predicate)	Various	Yes
Surface Electrodes	Various (Identical to predicate)	Various	Yes
Electrode Leads	Various (Identical to predicate)	Various	Yes

Specification/ Property	Subject Device NuVasive NVM5 System	Predicate Device NuVasive NVM5 System (K112718)	Substantially Equivalent?
Stimulating Probes	Various (Identical to predicate)	Various	Yes
Recording Channels	EMG, MEP, and SSEP	EMG, MEP, and SSEP	Yes
EMG			
EMG Modalities	• XLIF (Detection) • Basic & Dynamic Screw Test • Free Run EMG • Twitch Test (Train of Four)	• XLIF (Detection) • Basic & Dynamic Screw Test • Free Run EMG • Twitch Test (Train of Four)	Yes
XLIF (Detection)			
Types of Modes	Automatic Stimulation	Automatic Stimulation	Yes
Threshold Values for Color Alerts	Yes (Identical to predicate)	Yes	Yes
Audio feedback	Yes	Yes	Yes
Basic & Dynamic Screw Test			
Types of Modes	Automatic Stimulation	Automatic Stimulation	Yes
Threshold Values for Color Alerts	Yes (Identical to predicate)	Yes	Yes
Audio feedback	Yes	Yes	Yes
Free Run EMG			
Types of Modes	Manual Stimulation	Manual Stimulation	Yes
Threshold Values for Color Alert	Yes (Identical to predicate)	Yes	Yes
Audio feedback	Yes	Yes	Yes
Twitch Test (Train of Four)			
Types of Modes	Manual and Automatic Stimulation	Manual and Automatic Stimulation	Yes
Threshold Values for Color Alerts	Yes (Identical to predicate)	Yes	Yes
Audio feedback	Yes	Yes	Yes
TceMEP			
Types of Modes	Manual and Automatic Stimulation	Manual and Automatic Stimulation	Yes
Threshold Values for Color Alerts	Yes (Identical to predicate)	Yes	Yes
Audio feedback	Yes	Yes	Yes

Specification/ Property	Subject Device NuVasive NVM5 System	Predicate Device NuVasive NVM5 System (K112718)	Substantially Equivalent?
SSEP			
Types of Modes	Manual Stimulation	Manual Stimulation	Yes
Threshold Values for Color Alerts	Yes	No	Yes. Waveform output is the same regardless of background color.
Audio feedback	Yes	No	Yes. Waveform output is the same regardless of audio feedback.
Number of Recording Channels	10	10	Yes
Response Threshold	10-300 µV	10-300 µV	Yes
High Filter	1.5 kHz	1.5 kHz	Yes
Low Filter	0.030 kHz	0.030 kHz	Yes
Notch Filter	None	None	Yes
Audible EMG	Yes	Yes	Yes
CMRR	> 100 dB @ 60 Hz	> 100 dB @ 60 Hz	Yes
A/D Sampling Rate	9.6 kHz	9.6 kHz	Yes
Automatic Muting During Artifact	Yes	Yes	Yes
Stimulation Waveform	Rectangular, Monophasic Pulse	Rectangular, Monophasic Pulse	Yes
Constant Current/Voltage	Yes	Yes	Yes
Theoretical Max Voltage	300 V	300 V	Yes
Max Current	0.09 A	0.09 A	Yes
Max Pulse Width	0.0002 sec	0.0002 sec	Yes
Max Number of Pulses per second	5	5	Yes
Min Probe Surface Area	0.169 cm^2	0.169 cm^2	Yes

Table 3 – Comparison of Characteristics of the Subject NVM5 System *Guidance Function* vs. Predicate Devices

Specification/ Property	Subject Device	Predicate Devices			Substantially Equivalent
	NuVasive NVM5 System Guidance	**NuVasive NVM5 System Guidance (K112718)**	**Medtronic StealthStation® (K050438)**	**BrainLAB VectorVision® Trauma (K012448)**	
Indications for Use	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.	The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation procedures in the lumbar spine 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.	The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. *(Note: For the purposes of this predicate comparison the full indications have been limited.)*	BrainLAB VectorVision Trauma is intended to be a pre- and intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's pre- or intraoperative image data being processed by a VectorVision workstation. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a bone structure like tubular bones, pelvic, calcaneus and talus, or vertebra, can be identified relative to a CT, fluoroscopic, X-ray, or MR based model of the anatomy. Example procedures include but are not limited to: Spinal procedures and spinal implant procedures such as pedicle screw placement….*(Note: For the purposes of this predicate comparison the full indications have been limited.)*	Yes – the Guidance function has limited indications compared to the predicate.
Clinical Use	• Requires input derived from CT, MRI, or radiographic images • Intended to assist the surgeon in cannulating the pedicle based on user predefined trajectory • Integrated with EMG stimulation	• Requires input derived from CT, MRI, or radiographic images • Intended to assist the surgeon in cannulating the pedicle based on user predefined trajectory • Integrated with EMG stimulation	• Requires input derived from CT, MRI, or radiographic images • Intended to assist the surgeon in cannulating the pedicle based on user predefined trajectory • Integrated with EMG stimulation	• Requires input derived from CT, MRI, or radiographic images • Intended to assist the surgeon in cannulating the pedicle based on user predefined trajectory	Yes

Specification/ Property	Subject Device	Predicate Devices			Substantially Equivalent
	NuVasive NVM5 System Guidance	**NuVasive NVM5 System Guidance (K112718)**	**Medtronic StealthStation® (K050438)**	**BrainLAB VectorVision® Trauma (K012448)**	
Scientific Principles	• References angular sensing technology coupled with associated tracking instruments	• References angular sensing technology coupled with associated tracking instruments	• References angular and position sensing technology coupled with associated tracking instruments	• References angular and position sensing technology coupled with associated tracking instruments	Yes
	• Utilizes a C-Arm Reticle with radio dense markers	• Utilizes a C-Arm Reticle with radio dense markers	• Utilizes a C-Arm Reticle with radio dense markers	• Utilizes a C-Arm Reticle with radio dense markers	Yes
	• Uses accelerometers to sense angular measurements based on gravity by collecting 2 degrees of freedom (DOF) (rx, ry) data • Displays instrument orientation only (rotational information in the x and y planes only) with respect to gravity	• Uses accelerometers to sense angular measurements based on gravity by collecting 2 degrees of freedom (DOF) (rx, ry) data • Displays instrument orientation only (rotational information in the x and y planes only) with respect to gravity	• Uses infrared technology to capture positional and rotational information via 6 DOF (x, y, z; rx, ry, rz) data • Displays the location and orientation (positional and rotational information in the x, y, and z planes) of instruments in real time merged with pre-operatively obtained images of patient anatomy	• Uses infrared technology to capture positional and rotational information via 6 DOF (x, y, z; rx, ry, rz) data • Displays the location and orientation (positional and rotational information in the x, y, and z planes) of instruments in real time merged with pre-operatively obtained images of patient anatomy	Yes - The reduced degree of data collected by Guidance is still deemed substantially equivalent since it is used in conjunction with fluoroscopic imaging, not indicated for use by the predicate StealthStation. The amount of data collected by Guidance is sufficient to provide angular outputs to compare against the angular inputs identified by the user as the planned trajectory, considering that intraoperative radiographic imaging is used to confirm the starting point and correct trajectory of the cannulation needle.
Performance Requirements	• Angular tolerance of ±2° • Confirmation of alignment to pre-planned trajectory • Seamlessly integrated with an insulated Jamshidi Needle	• Angular tolerance of ±2° • Confirmation of alignment to pre-planned trajectory • Seamlessly integrated with an insulated Jamshidi Needle	• Angular tolerance of ±2° • Confirmation of alignment to pre-planned trajectory • Seamlessly integrated with an insulated Jamshidi Needle	• Confirmation of alignment to pre-planned trajectory *Others unknown*	Yes
Conformance to Standards	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	Yes
User Interface	Touch screen, graphical user interface and audio	Touch screen, graphical user interface and audio	Touch screen, graphical user interface and audio	Touch screen, graphical user interface and audio	Yes

Specification/ Property	Subject Device	Predicate Devices			Substantially Equivalent
	NuVasive NVM5 System Guidance	NuVasive NVM5 System Guidance (K112718)	Medtronic StealthStation® (K050438)	BrainLAB VectorVision® Trauma (K012448)	
System Materials/ Biosafety	Tracking instruments composed of known and accepted (biocompatible) materials.	Tracking instruments composed of known and accepted (biocompatible) materials.	Tracking instruments composed of known and accepted (biocompatible) materials.	Tracking instruments composed of known and accepted (biocompatible) materials.	Yes
System Sterilization	As selected for individual accessories, and validated to assure an SAL of 10^{-6}.	As selected for individual accessories, and validated to assure an SAL of 10^{-6}.	As selected for individual accessories, and validated to assure an SAL of 10^{-6}.	As selected for individual accessories, and validated to assure an SAL of 10^{-6}.	Yes

Table 4 – Comparison of Characteristics of the Subject NVM5 System *Bendini Function* vs. Predicate Device

Characteristics	Subject Device NVM5 System - Bendini Function	Predicate Devices Bendini Spinal Rod Bending System (K122742)	Substantially Equivalent?
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. [*Bendini function only shown below:*] • 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 NuVasive Bendini Spinal Rod Bending System 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.	YES
System Design	*Components:* Optical (IR) tracking technology system, IR tracking instruments, computer.	*Components:* Optical (IR) tracking technology system, IR tracking instruments, control unit, and mobile stand.	YES
	User Interface: Touch screen, graphical user interface and audio.	*User Interface:* Touch screen, graphical user interface and audio.	
	Conformance with Recognized Standards: IEC 60601-1, IEC 60601-1-2	*Conformance with Recognized Standards*: IEC 60601-1, IEC 60601-1-2	
	Power Supply – Line Input	*Power Supply* – Line Input	
Instrumentation	• IR Stylus (with integrated passive spheres) • Rod Bender	• IR Stylus (with integrated passive spheres) • Rod Bender	YES

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 well as electrical safety / compatibility testing, as follows:

- IEC 60601-1 (1988), A1 (1991), A2 (1995): Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC 60601-2-40 (1988): Medical Electrical Equipment Part 2-40:Particular requirements for the safety of electromyographs and evoked response equipment
- IEC 60601-1-2 (2001), A1 (2004): Medical Electrical Equipment Part 1-2: General Requirements for Safety Collateral Standard Electromagnetic Compatibility
- NVM5 System Verification and Validation Testing
- NVM5 System software Regression Testing
- Guidance performance data comparison from literature – data from clinical literature demonstrated substantial equivalence of the subject device to the predicates BrainLAB VectorVision Trauma and Medtronic StealthStation for lumbosacral levels: (1) *Accuracy of percutaneous lumbar pedicle screw placement using the oblique or "owl's-eye" view and novel guidance technology* (J Neurosurg Spine, 2010) and (2) *Placement of thoracolumbar pedicle screws using three-dimensional image guidance: experience in a large patient cohort* (J Neurosurg Spine, 2009)].
- Nonclinical testing performed for the *Bendini* function included evaluation of software performance per predetermined specifications outlined in the SRS, GUI functionality, error handling, system accuracy during data acquisition, verification of instrument performance in combination with the software, and verification of software algorithms.

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, and safe and effective for its intended use.

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

April 23, 2013

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

Re: K123307
Trade/Device Name: NuVasive NVM5 System
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: PDQ, ETN, GWF, HAW, IKN, OLO
Dated: March 15, 2013
Received: March 20, 2013

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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting 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): K123307

Device Name: NVM5 System

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.

- 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.

- TcMEP – Transcranial stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract. The TcMEP 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.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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