June 29, 2018

NuVasive, Incorporated
Olga Lewis
Regulatory Affairs Senior Manager
7475 Lusk Blvd.
San Diego, California 92121

Re: K180038
Trade/Device Name: NuVasive® *Pulse*™ *System*
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, PDQ, ETN, GWF, HAW, IKN, OWB, LLZ, JAA
Dated: May 31, 2018
Received: June 1, 2018

Dear Olga Lewis:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180038

Device Name
NuVasive® *Pulse™ System*

Indications for Use *(Describe)*

The Pulse System is a medical device comprised of Pulse NVM5, Pulse LessRay, and Pulse Navigation.

The Pulse NVM5 is intended for intraoperative neurophysiologic monitoring during spinal surgery, neck dissections, thoracic surgeries, and upper and lower extremities. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. The Pulse 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. 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 Access - The remote monitoring and local wireless control provides real-time capabilities to the Pulse System.

• 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 Pulse LessRay is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.

Pulse Navigation is intended as an intraoperative image-guided localization system in either open or minimally-invasive spinal surgical procedures. Instruments and implants tracked by a passive marker sensor system are virtually displayed on a patient's 2D or 3D radiographic image data. The system enables computer-assisted navigation for spinal surgical procedures in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure can be identified relative to the acquired image of the anatomy.

This may include the following spinal implant procedures:

o Pedicle Screw Placement (2D Navigation in Sacral and Lumbar Spine and 3D Navigation in Sacral and Thoracolumbar Spine)

o Interbody Device Placement (2D and 3D Navigation in Lumbar Spine via Lateral Approach)

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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510(k) Summary K180038

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:

Olga Lewis
Senior Manager, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: June 29, 2018

B. Device Name

Proprietary Name:	NuVasive® *Pulse™ System*
Common or Usual Name:	Neurological Surgical Monitor; Image-intensified fluoroscopic x-ray system Stereotaxic instrument
Classification Name:	Stereotaxic Instrument
Device Class:	Class II
Classification:	21 CFR §882.4560
Product Code:	OLO, PDQ, ETN, GWF, HAW, IKN, OWB, LLZ, JAA

C. Predicate Devices

The subject *NuVasive Pulse System* is substantially equivalent to the primary predicate *NuVasive Next Generation NVM5 System* (K162313). It is also substantially equivalent to the additional predicate devices *LessRay System* (K173314), *StealthStation S8 Spine Software V1.0.0* (K170011), and NuVasive *Navigation Instruments* (K172623).

D. Device Description

The *Pulse System* is a medical device consisting of *Pulse NVM5*, *Pulse LessRay*, and *Pulse Navigation*. The *Pulse System* hardware includes a Patient Module (PM) and computer, as well as accompanying accessory components.

The *Pulse NVM5* is a medical device that is intended for intraoperative neurological monitoring and status assessment during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurological status. The *Pulse 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 the muscle groups innervated by the 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 *Pulse NVM5 System* includes a software function that measures spinal parameters and acquires the location of spinal implants (screws, hooks) to assist the surgeon in

bending spinal rods (*Bendini*). Lastly, the *Pulse NVM5* provides Remote Access in two pathways, Local Wireless Control and Remote Monitoring.

LessRay is a software application which can be interfaced to a fluoroscope with a video cable. The images produced by the fluoroscope are transmitted to a frame grabber in the computer running LessRay where the images are enhanced and then displayed. When used in connection with the low dose and/or pulse setting on the fluoroscope, the user can improve the quality (clarity, contrast, noise level, and usability[i]) of a noisy (low-quality) image. Using this system, much of the graininess of low radiation dose images can be eliminated. This allows for greater utility of low dose imaging.[ii] LessRay provides the additional feature of being able to interface LessRay with a tracking system in order to aid the C-arm technician in positioning the fluoroscope between the various views of the patient necessary for the intervention. LessRay with Tracking ensures that the fluoroscope is centered over the correct anatomy prior to taking any additional x-ray images.

LessRay System has additional capability of instrument tracking to aid the user in positioning an instrument using prior baseline x-rays. A tracker is attached to the instrument and as the instrument moves, the tracking system connected to LessRay tracks the location of the instrument. LessRay System uses this information to aid the user in positioning the instrument.

Pulse Navigation is a stereotactic surgical application intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. It is intended for intraoperative image-guided localization which allows for surgical instruments to be tracked in three dimensional space. The device provides real-time information directly to the surgeon, enabling the surgeon to evaluate the instrument depth and trajectory for computer-assisted navigation during spine surgery. Instruments are tracked in three dimensional space with an Infrared (IR) Camera, being virtually displayed and superimposed on registered radiographic images. Radiographic images can be either 2D fluoroscopic images (C-arm) or 3D intraoperative scan (CT or Cone Beam CT).

E. Indications for Use

The *Pulse System* is a medical device comprised of *Pulse NVM5*, *Pulse LessRay*, and *Pulse Navigation*.
The *Pulse NVM5* is intended for intraoperative neurophysiologic monitoring during spinal surgery, neck dissections, thoracic surgeries, and upper and lower extremities. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. The *Pulse 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. 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 Access - The remote monitoring and local wireless control provides real-time capabilities to the Pulse System.
- 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 *Pulse LessRay* is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.

Pulse Navigation is intended as an intraoperative image-guided localization system in either open or minimally-invasive spinal surgical procedures. Instruments and implants tracked by a passive marker sensor system are virtually displayed on a patient's 2D or 3D radiographic image data. The system enables computer-assisted navigation for spinal surgical procedures in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure can be identified relative to the acquired image of the anatomy.
This may include the following spinal implant procedures:

- Pedicle Screw Placement (2D Navigation in Sacral and Lumbar Spine and 3D Navigation in Sacral and Thoracolumbar Spine)
- Interbody Device Placement (2D and 3D Navigation in Lumbar Spine via Lateral Approach)

F. Technological Characteristics

As was established in this submission, the subject *Pulse 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 device through comparison in areas including design, intended use, material composition, and functions.

Table 1 – Comparison of Technical Characteristics

Specification/ Property	Predicate Device **NuVasive Next Generation NVM5 System (K162313)**	Predicate Device **LessRay System (K173314)**	Predicate Device **StealthStation S8 Spine Software v1.0.0 (Medtronic– K170011)**	Subject Device **Pulse System**
Intended Use / Indications for Use	The *Next Generation NVM5® System* is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery, neck dissections, thoracic surgeries, and upper and lower extremities. 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.	*LessRay System* is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.	The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System, with StealthStation Spine Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures. Their use 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 spine or pelvis, can be identified relative to images of the anatomy. This can include the following spinal implant procedures, such as: • Pedicle Screw Placement • Iliosacral Screw Placement • Interbody Device Placement	The *Pulse System* is a medical device comprised of *Pulse NVM5, Pulse LessRay*, and *Pulse Navigation.* The *Pulse NVM5* is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery, neck dissections, thoracic surgeries, and upper and lower extremities. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. *Pulse 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.

Specification/ Property	Predicate Device **NuVasive Next Generation NVM5 System (K162313)**	Predicate Device **LessRay System (K173314)**	Predicate Device **StealthStation S8 Spine Software v1.0.0 (Medtronic– K170011)**	Subject Device **Pulse System**
Intended Use / Indications for Use (***Continued***)	• 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 Access - The remote monitoring and local wireless control provides real-time capabilities to the NG NVM5 System for additional physicians. • 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.			• Remote Access - The remote monitoring and local wireless control provides real-time capabilities to the Pulse System • 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 *Pulse LessRay* is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease. *Pulse Navigation* is intended as an intraoperative image-guided localization system in either open or minimally-invasive spinal surgical procedures. Instruments and implants tracked by a passive marker sensor system are virtually displayed on a patient's 2D or 3D radiographic image data. The system enables computer-assisted navigation for spinal surgical procedures in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure can be identified relative to the acquired image of the anatomy. This may include the following spinal implant procedures: o Pedicle Screw Placement (2D Navigation in Sacral and Lumbar Spine and 3D Navigation in Sacral and Thoracolumbar Spine) o Interbody Device Placement (2D and 3D Navigation in Lumbar Spine via Lateral Approach)
Device Class	II	II	II	II
Product Code	PDQ, ETN, GWF, HAW, IKN, OLO,	OWB, LLZ, JAA	OLO	OLO, PDQ, ETN, GWF, HAW, IKN, OWB, LLZ, JAA
Regulation Number (21CFR)	§874.1820, §882.1870, §882.4560, §890.1375	§892.1650	§882.4560	§882.4560, §874.1820, §882.1870, §890.1375, §892.1650,
Device Classification Name	Surgical nerve stimulator/locator; Evoked response electrical stimulator; Neurological stereotaxic instrument; Electromyography (EMG) monitor/stimulator	Image-intensified fluoroscopic x-ray system	Stereotaxic Instrument	Surgical nerve stimulator/locator; Evoked response electrical stimulator; Neurological stereotaxic instrument; Electromyography (EMG) monitor/stimulator Image-intensified fluoroscopic x-ray system; Stereotaxic Instrument

Specification/ Property	Predicate Device **NuVasive Next Generation NVM5 System (K162313)**	Predicate Device **LessRay System (K173314)**	Predicate Device **StealthStation S8 Spine Software v1.0.0 (Medtronic– K170011)**	Subject Device **Pulse System**
Functionalities	• XLIF Detection • Basic & Dynamic Screw Test • Free Run EMG • Twitch Test (Train of Four) • MEP • SSEP • Remote Access • Bendini • NuvaMap O.R. • NuvaLine spinal parameter assessment tools - *Optional*	• Software based device used to provide computer display systems interfaced to fluoroscope through a video cable. The images produced by the fluoroscope are transmitted through a cable to a frame capture board in the computer where the images are enhanced and then displayed on the monitor. • Enhanced images are displayed on a computer monitor at the same time that the corresponding original image is displayed on the fluoroscope monitor(s). • Uses software to control the frame capture, intermediate image manipulation, and subsequent image display. • The delay between frame acquisition and frame display is less than the time between frames, i.e. 33 msec. • Serves only as an image display which is in addition to the fluoroscope's standard image display device. Device is passive, in that the operation depends only on the video output of the fluoroscope, and it does not transmit any signals or images to the fluoroscope.	StealthStation Spine Software functionality is described in terms of its feature sets which are categorized as imaging modalities, registration, planning, interfaces with medical devices, and views. Feature sets include functionality that contributes to clinical decision making and are necessary to achieve system performance.	• XLIF Detection • Basic & Dynamic Screw Test • Free Run EMG • Twitch Test (Train of Four) • MEP • SSEP • Remote Access • Bendini • NuvaMap O.R. • NuvaLine spinal parameter assessment tools - *Optional* • LessRay Image Enhancement • LessRay C-arm tracking • LessRay Instrument Tracking • Navigation: imaging modalities, registration, interfaces with medical devices, and views.

Specification/ Property	Predicate Device **NuVasive Next Generation NVM5 System (K162313)**	Predicate Device **LessRay System (K173314)**	Predicate Device **StealthStation S8 Spine Software v1.0.0 (Medtronic– K170011)**	Subject Device **Pulse System**
Algorithms	• XLIF Detection • Basic & Dynamic Screw Test • Free Run EMG • Twitch Test (Train of Four) • MEP • SSEP • Bendini – Rod bending and spinal parameter assessment	• Image quality improvement using averaging algorithm • Contrast and brightness enhancement with simultaneous reduction of random noise	Unknown	• XLIF Detection • Basic & Dynamic Screw Test • Free Run EMG • Twitch Test (Train of Four) • MEP • SSEP • Bendini – Rod bending and spinal parameter assessment • Image quality improvement using averaging algorithm • Contrast and brightness enhancement with simultaneous reduction of random noise
Total Available Channels	32			32
Headbox/ Patient Module	Digital Preamplifier with A/D Converter		Unknown	Digital Preamplifier with A/D Converter
IEC 60601-1 Compliant	Yes	Yes	Yes	Yes
User Interface	NuVasive supplied computer with separate touch screen and/or keyboard/mouse Mobile device			NuVasive supplied computer with separate touch screen and/or keyboard/mouse Mobile device
User Comments	Free form text entry saved with time marks			Free form text entry saved with time marks
Video Inputs	Yes			Yes
Network Compatible	Yes			Yes
Embedded Help	Yes			Yes
Artifact Rejection	User Defined and automatic			User Defined and automatic
Remote Access	Remote Access includes Remote Reader Monitoring Client and Local Wireless Control			Remote Access includes Remote Reader Monitoring Client and Local Wireless Control
Needle Electrodes	Various			Various
Surface Electrodes	Dual Surface Ag-AgCl Film and Hydrogel			Dual Surface Ag-AgCl Film and Hydrogel
EMG Endotracheal tube	Yes with integrated electrodes for intraoperative monitoring			Yes with integrated electrodes for intraoperative monitoring
Electrode Leads	Various			Various

Specification/ Property	Predicate Device NuVasive Next Generation NVM5 System (K162313)	Predicate Device LessRay System (K173314)	Predicate Device StealthStation S8 Spine Software v1.0.0 (Medtronic– K170011)	Subject Device Pulse System
Stimulating Probes	Various			Various
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)
Types of Modes	Automatic Stimulation (red/yellow/green)			Automatic Stimulation (red/yellow/green)
Threshold Values for Red/Yellow/Green	Yes			Yes
Audio feedback	Yes			Yes
Interpretation for alerts	Green = Nerve in close proximity Yellow = Nerve in closer proximity Red = Nerve in very close proximity			Green = Nerve in close proximity Yellow = Nerve in closer proximity Red = Nerve in very close proximity
EMG Monitoring	Continuous free running and stimulated (triggered)			Continuous free running and stimulated (triggered)
Recording Channels	10			10
Audible EMG	Yes			Yes
Automatic Muting During Artifact	Yes			Yes
Train of Four Testing	Yes			Yes
MEP Types of Modes	• Alert (red/green) – transcranial MEP only • Threshold (red/yellow/green) Stimulation – transcranial and lumbar MEP			• Alert (red/green) – transcranial MEP only • Threshold (red/yellow/green) Stimulation – transcranial and lumbar MEP
Recording Channels	10			10

Specification/ Property	Predicate Device **NuVasive Next Generation NVM5 System (K162313)**	Predicate Device **LessRay System (K173314)**	Predicate Device **StealthStation S8 Spine Software v1.0.0 (Medtronic– K170011)**	Subject Device **Pulse System**
Audible MEP/EMG	Yes			Yes
Automatic Muting During Artifact	Yes			Yes
SSEP Types of Modes	Manual Stimulation (SSEP Standard and "SSEP Alert" with automatic color background alerts and anatomical representation)			Manual Stimulation (SSEP Standard and "SSEP Alert" with automatic color background alerts and anatomical representation)
Threshold Values for Red/Yellow/Green	Yes (Green/Yellow only for simplified SSEP Harness and Red/Yellow/Green for Standard SSEP Harness)			Yes (Green/Yellow only for simplified SSEP Harness and Red/Yellow/Green for Standard SSEP Harness)
Audio feedback	Yes			Yes
Recording Channels	8			8

Specification/ Property	Predicate Device NuVasive Next Generation NVM5 System (K162313)	Predicate Device LessRay System (K173314)	Predicate Device StealthStation S8 Spine Software v1.0.0 (Medtronic– K170011)	Subject Device Pulse System
C-arm Tracking		• When tracking is enabled, will automatically choose the Baseline when the fluoroscope is near the location and orientation that the Baseline was initially taken. • When tracking is enabled, requires hardware components in order to mount the off-the-shelf tracking hardware to the C-arm and to the operating table. • When tracking is enabled, requires the use of an off-the-shelf tracking system in order to track the 6 DOF location of the C-arm relative to the operating table. When tracking is enabled, visual cues are provided which help guide the user in positioning the C-arm back to where a prior Baseline was taken.		• When tracking is enabled, will automatically choose the Baseline when the fluoroscope is near the location and orientation that the Baseline was initially taken. • When tracking is enabled, requires hardware components in order to mount the off-the-shelf tracking hardware to the C-arm and to the operating table. • When tracking is enabled, requires the use of an off-the-shelf tracking system in order to track the 6 DOF location of the C-arm relative to the operating table. When tracking is enabled, visual cues are provided which help guide the user in positioning the C-arm back to where a prior Baseline was taken.
Tracking Options		Optical		Optical
Instrument Tracking		NuVasive LessRay System has additional capability of instrument tracking to aid the user in positioning an instrument using prior baseline x-rays.		Pulse LessRay has additional capability of instrument tracking to aid the user in positioning an instrument using prior baseline x-rays.
Imaging Modalities			X-Ray Based Imaging	X-Ray Based Imaging
Registration Features			PointMerge Registration SurfaceMerge Registration FluoroMerge Registration Automatic 2D Image Registration Automatic 3D Image Registration	Automatic 2D Image Registration Automatic 3D Image Registration
Planning Features			Plan Entry and Target Selection 3D Model Building Deformity Planning	n/a

Specification/ Property	Predicate Device NuVasive Next Generation NVM5 System (K162313)	Predicate Device LessRay System (K173314)	Predicate Device StealthStation S8 Spine Software v1.0.0 (Medtronic– K170011)	Subject Device Pulse System
Medical Device Interfaces			O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm ISO-C 3D C-Arm Orbic 3D C-Arm	O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm Mobius Airo
View (Display Features)			Look Sideways 3D Anatomic Orthogonal Trajectory 1 and 2 Trajectory Guidance Look Ahead Probe's Eye AP and Lateral Synthetic AP and Lateral Maximum Intensity Projection Video Input	3D Anatomic Orthogonal Trajectory 1 and 2 Probe's Eye AP and Lateral Synthetic AP and Lateral
Software Interface (GUI)			Basic gray and black style with 4 main tasks and tab interface to access tools. Controls on the right.	Basic grey and black style with tab interface to access tools and controls.
Scanner Interface Technology (to imaging devices)			Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Network Connectivity CD, DVD, USB DICOM Import
Localization Technology			Optical	Optical

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *Pulse System* is substantially equivalent to other predicate devices and to verify that the *Pulse System* meets design specifications and performance characteristics, based upon the intended use. The *Pulse System* was subjected to the following verification and validation testing according to the software requirements specifications defined for the system.

- Tracking accuracy verification per ASTM F2554-10
- Accessories attachment verification
- 2D navigation distortion and calibration verification
- 3D navigation segmentation and tracking error verification
- Navigation software validation
- Cadaver validation for 2D and 3D navigation for pedicle screw and interbody device placement
- System integration testing

The results of these studies showed that the subject *Pulse System* meets software requirements defined for the system and satisfies same acceptance criteria as the performance of the predicate device. Therefore, subject *Pulse System* was found to be substantially equivalent.

H. Conclusions

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

[i] As evaluated by a human observer in a side by side visual comparison of 30 image pairs with and without LessRay processing.

[ii] In clinical practice, the amount of image quality improvement achieved when a Pulsed and/or Low Dose image is processed with LessRay is dependent on the clinical task, patient size, anatomical location, and clinical practice. The dose should be set at a level to which the physician is able to achieve the adequate image quality needed for the particular clinical task. A consultation with a radiologist and a physicist may aid in determining the appropriate dose settings.