July 29, 2021

NuVasive, Incorporated
Emily Chung
Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K210574
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: June 28, 2021
Received: June 29, 2021

Dear Emily Chung:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210574

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.

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.

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 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 (cervical, thoracic, lumbar)
- Iliosacral screw placement

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 **K210574**

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:

Manthan J. Damani
Manager, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: July 28, 2021

B. Device Name

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

C. Predicate Devices

The subject *NuVasive Pulse System* is substantially equivalent to the primary predicate *NuVasive Pulse System* (K180038). It is also substantially equivalent to the additional predicate devices *StealthStation S8 Spine Software V1.0.0* (K170011), and *NuVasive Navigation.S Instruments* (K200719).

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 control unit, 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.

Pulse 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.

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 are in the form of 3D intraoperative scan (CT or Cone Beam CT).

The reason for this submission is to update indications for use for the *Pulse Navigation* application and to introduce design modifications to hardware and software components of the Navigation application.

E. Indications for Use

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

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.

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 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 (cervical, thoracic, lumbar)
- Iliosacral screw placement

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 Pulse System (K180038)**	Predicate Device **StealthStation S8 Spine Software v1.0.0 (K170011)**	Subject Device **Pulse System**	Comments/ If not identical, SE rationale
Intended Use / Indications for Use	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.	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*. *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.	**Substantially Equivalent.** Testing has been completed and successfully demonstrated that these differences in indications for use have no impact on device performance when compared to the predicate device and do not introduce any new risks or impact any existing risks. Therefore, these differences do not impact safety or effectiveness of the subject device when compared to the predicate devices.

Specification/ Property	Predicate Device **NuVasive Pulse System (K180038)**	Predicate Device **StealthStation S8 Spine Software v1.0.0 (K170011)**	Subject Device **Pulse System**	Comments/ **If not identical, SE rationale**
Intended Use / Indications for Use (***Continued***)	• 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)		• 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 *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 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 (cervical, thoracic, lumbar) o Iliosacral screw placement	
Device Class	II	II	II	**Identical**
Product Code	OLO, PDQ, ETN, GWF, HAW, IKN, OWB, LLZ, JAA	OLO	OLO, PDQ, ETN, GWF, HAW, IKN, OWB, LLZ, JAA	**Identical (Incorporates all product codes)**
Regulation Number (21CFR)	§882.4560, §874.1820, §882.1870, §890.1375, §892.1650	§882.4560	§882.4560, §874.1820, §882.1870, §890.1375, §892.1650	**Identical (Incorporates all regulation numbers)**
Device Classification Name	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	Stereotaxic Instrument; Surgical nerve stimulator/locator; Evoked response electrical stimulator; Neurological stereotaxic instrument; Electromyography (EMG) monitor/stimulator; Image-intensified fluoroscopic x-ray system.	**Identical (Incorporates all Device Classification Names)**

Specification/ Property	Predicate Device **NuVasive Pulse System (K180038)**	Predicate Device **StealthStation S8 Spine Software v1.0.0 (K170011)**	Subject Device **Pulse System**	Comments/ **If not identical, SE rationale**
Functionalities	1. XLIF Detection 2. Basic & Dynamic Screw Test 3. Free Run EMG 4. Twitch Test (Train of Four) 5. MEP 6. SSEP 7. Remote Access 8. Bendini 9. NuvaMap O.R. 10. NuvaLine spinal parameter assessment tools - *Optional* 11. LessRay Image Enhancement 12. LessRay C-arm tracking 13. LessRay Instrument Tracking 14. Navigation: imaging modalities, registration, interfaces with medical devices, and views.	15. 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 (which includes trajectory projections and save virtual screw positions) and are necessary to achieve system performance.	1. XLIF Detection 2. Basic & Dynamic Screw Test 3. Free Run EMG 4. Twitch Test (Train of Four) 5. MEP 6. SSEP 7. Remote Access 8. Bendini 9. NuvaMap O.R. 10. NuvaLine spinal parameter assessment tools - Optional 11. LessRay Image Enhancement 12. LessRay C-arm tracking 13. Navigation: imaging modalities, registration, interfaces with medical devices, and views; screw planning (screw placement and trajectory saving).	**Substantially Equivalent.** The addition of screw planning is the only difference in the subject Pulse System and the predicate Pulse System. The StealthStation S8 predicate allows the user to use trajectory projections and save virtual screw positions. In the Subject Device these features are referred to as trajectory saving and screw placement, respectively. Testing has been completed and successfully demonstrated that these differences in functionality have no impact on device performance when compared to the predicate device and do not introduce any new risks or impact any existing risks. Therefore, these differences do not impact safety or effectiveness of the subject device when compared to the predicate devices.
Algorithms	1. XLIF Detection 2. Basic & Dynamic Screw Test 3. Free Run EMG 4. Twitch Test (Train of Four) 5. MEP 6. SSEP 7. Bendini – Rod bending and spinal parameter assessment 8. Image quality improvement using averaging algorithm 9. Contrast and brightness enhancement with simultaneous reduction of random noise 10. Registration 11. Instrument Confirmation	1. Trajectory projections and save virtual screw positions 2. Other algorithm features	1. XLIF Detection 2. Basic & Dynamic Screw Test 3. Free Run EMG 4. Twitch Test (Train of Four) 5. MEP 6. SSEP 7. Bendini – Rod bending and spinal parameter assessment 8. Image quality improvement using averaging algorithm 9. Contrast and brightness enhancement with simultaneous reduction of random noise 10. Registration 11. Instrument Confirmation 12. Screw planning (screw placement and trajectory saving)	**Substantially Equivalent.** The addition of screw planning is the only difference in the subject Pulse System and the predicate Pulse System. The StealthStation S8 predicate allows the user to use trajectory projections and save virtual screw positions. In the Subject Device these features are referred to as trajectory saving and screw placement, respectively. Testing has been completed and successfully demonstrated that these differences in the algorithms have no impact on device performance when compared to the predicate device and do not introduce any new risks or impact any existing risks. Therefore, these differences do not impact safety or effectiveness of the subject device when compared to the predicate devices.
Headbox/ Patient Module	Digital Preamplifier with A/D Converter	Unknown	Digital Preamplifier with A/D Converter	**Identical**
IEC 60601-1 Compliant	Yes	Yes	Yes	**Identical**
Impedance Test	Automatic		Automatic	**Identical**
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	**Identical**
User Comments	Free form text entry saved with time marks		Free form text entry saved with time marks	**Identical**
Video Inputs	Yes		Yes	**Identical**
Network Compatible	Yes		Yes	**Identical**
Embedded Help	Yes		Yes	**Identical**
Artifact Rejection	User Defined and Automatic		User Defined and Automatic	**Identical**
Remote Access	Remote Access includes Remote Reader Monitoring Client and Local Wireless Control		Remote Access includes Remote Reader Monitoring Client and Local Wireless Control	**Identical**
Needle Electrodes	Various		Various	**Identical**
Surface Electrodes	Dual Surface Ag-AgCl Film and Hydrogel		Dual Surface Ag-AgCl Film and Hydrogel	**Identical**

Specification/ Property	Predicate Device NuVasive Pulse System (K180038)	Predicate Device StealthStation S8 Spine Software v1.0.0 (K170011)	Subject Device Pulse System	Comments/ If not identical, SE rationale
EMG Endotracheal tube	Yes with integrated electrodes for intraoperative monitoring		Yes with integrated electrodes for intraoperative monitoring	**Identical**
Electrode Leads	Various		Various	**Identical**
Stimulating Probes	Various		Various	**Identical**
EMG				
EMG Modalities	3.0XLIF (Detection) 4.0Basic & Dynamic Screw Test 5.0Free Run EMG 6.0Twitch Test (Train of Four)		a) XLIF (Detection) b) Basic & Dynamic Screw Test c) Free Run EMG d) Twitch Test (Train of Four)	**Identical**
Types of Modes	Automatic Stimulation (red/yellow/green)		Automatic Stimulation (red/yellow/green)	**Identical**
Threshold Values for Red/Yellow/Green	Yes		Yes	**Identical**
Audio feedback	Yes		Yes	**Identical**
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	**Identical**
Types of Modes	Manual Stimulation		Manual Stimulation	**Identical**
EMG Monitoring	Continuous free running and stimulated (triggered)		Continuous free running and stimulated (triggered)	**Identical**
Audible EMG	Yes		Yes	**Identical**
Automatic Muting During Artifact	Yes		Yes	**Identical**
Train of Four Testing	Yes		Yes	**Identical**
MEP				
MEP Types of Modes	1. Alert (red/green) – transcranial MEP only 2. Threshold (red/yellow/green) Stimulation – transcranial and lumbar MEP		1. Alert (red/green) – transcranial MEP only 2. Threshold (red/yellow/green) Stimulation – 3. transcranial and lumbar MEP	**Identical**
Threshold Values for Red/Yellow/Green	Yes		Yes	**Identical**
Audio feedback	Yes		Yes	**Identical**
Audible MEP/EMG	Yes		Yes	**Identical**
Automatic Muting During Artifact	Yes		Yes	**Identical**
SSEP				
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)	**Identical**
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)	**Identical**

Specification/ Property	Predicate Device NuVasive Pulse System (K180038)	Predicate Device StealthStation S8 Spine Software v1.0.0 (K170011)	Subject Device Pulse System	Comments/ If not identical, SE rationale
Audio feedback	Yes		Yes	**Identical**
LessRay				
C-arm Tracking	●When tracking is enabled, LessRay will automatically choose the Baseline when the fluoroscope is near the location and orientation that the Baseline was initially taken. ●When tracking is enabled, LessRay requires hardware components in order to mount the tracking hardware to the C-arm and to the operating table. ●When tracking is enabled, LessRay 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, Pulse LessRay will automatically choose the Baseline when the fluoroscope is near the location and orientation that the Baseline was initially taken. ●When tracking is enabled, Pulse LessRay requires hardware components in order to mount the tracking hardware to the C-arm and to the operating table. ●When tracking is enabled, Pulse LessRay 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.	**Identical**
Tracking Options	Optical		Optical	**Identical**
Instrument Tracking	Pulse LessRay 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.	**Identical**
Navigation				
Imaging Modalities	X-Ray Based Imaging	X-Ray Based Imaging	X-Ray Based Imaging	**Identical**
Registration Features	Automatic 2D Image Registration Automatic 3D Image Registration	PointMerge Registration SurfaceMerge Registration FluoroMerge Registration Automatic 2D Image Registration Automatic 3D Image Registration	Automatic 3D Image Registration	**Identical**
Planning Features	n/a	Plan Entry and Target Selection 3D Model Building Deformity Planning	Screw planning (screw placement and trajectory saving)	**Substantially Equivalent.** The StealthStation S8 predicate allows the user to use trajectory projections and save virtual screw positions. In the Subject Device these features are referred to as trajectory saving and screw placement, respectively. Testing has been completed and successfully demonstrated that these differences in the planning features have no impact on device performance when compared to the predicate device and do not introduce any new risks or impact any existing risks. Therefore, these differences do not impact safety or effectiveness of the subject device when compared to the predicate devices.

Specification/ Property	Predicate Device **NuVasive Pulse System (K180038)**	Predicate Device **StealthStation S8 Spine Software v1.0.0 (K170011)**	Subject Device **Pulse System**	**Comments/ If not identical, SE rationale**
Medical Device Interfaces	O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm Mobius Airo	O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm ISO-C 3D C-Arm Siemens Orbic 3D C-Arm	O-arm Imaging System Ziehm Vision RFD 3D C-Arm Siemens Cios Spin	**Substantially Equivalent.** The Siemens Cios Spin and Ziehm RFD 3D are 2D and 3D fluoroscopic imaging devices. They are similar in technology and function to the Siemens Orbic 3D C-arm, which is a predecessor to the Siemens Cios Spin. Both devices are indicated for intraoperative imaging for spine surgery and cleared by FDA. Testing has been completed and successfully demonstrated that these differences in the medical device interfaces have no impact on device performance when compared to the predicate device and do not introduce any new risks or impact any existing risks. Therefore, these differences do not impact safety or effectiveness of the subject device when compared to the predicate devices.
View (Display Features)	3D Anatomic Orthogonal Trajectory 1 and 2 Probe's Eye AP and Lateral Synthetic AP and Lateral	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 Axial CT (Trajectory 1) Sagittal CT (Trajectory 2) Probe's Eye Axial DRR Sagittal DRR (Synthetic Lateral) Coronal DRR (Synthetic AP)	**Substantially Equivalent.** The Axial CT and Sagittal CT views are different names for the Trajectory 1 and 2 views – they are equivalent in function. The Sagittal DRR and Coronal DRR views are different names for the Synthetic Lateral and Synthetic AP views, respectively – they are equivalent in function. The Axial DRR image is created the same way as the Sagittal DRR and the Coronal DRR views, but from the third plane of the CT 3D volume. The function is equivalent to the Sagittal DRR and Coronal DRR view, but from a different visual perspective. Testing has been completed and successfully demonstrated that these differences in the view/display features have no impact on device performance when compared to the predicate device and do not introduce any new risks or impact any existing risks. Therefore, these differences do not impact safety or effectiveness of the subject device when compared to the predicate devices.
Software Interface (GUI)	Basic grey and black style with tab interface to access tools and controls.	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.	**Identical**
Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM Import	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Network Connectivity USB DICOM Import	**Substantially Equivalent.** Both predicates allow Network Connectivity, USB, and DICOM import interface technology, which is identical to the subject device. CD and DVD interface was removed from scope of subject device as this technology is no longer required. Testing has been completed and successfully demonstrated that these differences in the scanner interface technology have no impact on device performance when compared to the predicate device and do not introduce any new risks or impact any existing risks. Therefore, these differences do not impact safety or effectiveness of the subject device when compared to the predicate devices.

Specification/ Property	Predicate Device NuVasive Pulse System (K180038)	Predicate Device StealthStation S8 Spine Software v1.0.0 (K170011)	Subject Device Pulse System	Comments/ If not identical, SE rationale
Localization Technology	Optical	Optical	Optical	**Identical**

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 product and software requirements specifications defined for the system.

- Tracking accuracy verification per ASTM F2554-10
- 3D navigation registration and tracking error verification
- Navigation software validation
- Cadaver validation for 3D navigation for pedicle screw placement
- Electrical safety and EMC testing per IEC 60601
- Navigation system accuracy performance

The results of these studies demonstrated that the subject *Pulse System* meets product and software requirements defined for the system and satisfies the same acceptance criteria as the performance of the predicate device. Therefore, the 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.