January 10, 2025

Globus Medical, Inc
Jennifer Antonacci
Group Manager, Regulatory Affairs
Valley Forge Business Center
2560 General Armistead Ave
Audubon, Pennsylvania 19403

Re: K243814
Trade/Device Name: Pulse ICT Adapter
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 11, 2024
Received: December 11, 2024

Dear Jennifer Antonacci:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243814

Device Name
NuVasive Pulse System

Indications for Use *(Describe)*
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:

Prem Pisupati
Lead Regulatory Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: 08-Jan-2025

B. Device Name

Trade or Proprietary Name:	NuVasive® Pulse™ System
Common or Usual Name:	Stereotaxic Instrument
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

Primary Predicate: NuVasive Pulse System (K210574)
Other Predicates: ExcelsiusGPS (K171651 and K191100)

D. Device Description

The subject device, Pulse ICT Adapter is introducing compatibility based on the design of existing fiducial-based registration via patient reference hardware, the Spinous Process Clamp (Pulse System K210574) and Globus Medical ICT Fixture (ExcelsiusGPS K171651 and K191100). The subject device, Pulse ICT Adapter was designed to offer surgeons more flexibility during the registration process of Pulse

Navigation by providing an additional patient reference hardware design option by attaching the existing Globus Medical Intra-Op CT Fixture to the following: existing Articulating Arm and Bedrail Clamp. Despite the changes introduced to predicate Spinous Process Clamp (K210574), the subject device Pulse ICT Adapter is substantially equivalent to the predicate as demonstrated by verification and validation testing performed using well established and previously cleared test methods.

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) 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. 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 the submission is to introduce a new intra-operative CT (ICT) adapter for use with the ExcelsiusGPS ICT Registration Fixture for the Pulse Navigation application.

E. Indications for Use

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

The introduction of new hardware (the Pulse ICT Adapter) and a new registration algorithm in software allows an updated fiducial-based patient registration method, when used together with ExcelsiusGPS ICT fixture. The subject device is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principles of operation.

Characteristics	Subject Device: NuVasive Pulse System Fiducial based registration (ICT Fixture and Pulse ICT adapter)	Predicate Device: NuVasive Spinous Process Clamp (K210574)	Predicate Device: Globus Medical Intra-op CT Registration Fixture (ICT Fixture) ExcelsiusGPS (K171651 & K191100)
Principle of Operation	Fiducial registration hardware provides a reference to a rigid anatomical structure.	Patient reference hardware provides a reference to a rigid anatomical structure.	Patient reference hardware that provides a reference to a rigid anatomical structure.
System Components	Pulse ICT Adapter and ExcelsiusGPS ICT Fixture are	Clamps directly attached to spinous process	ICT fixture attached to patient reference hardware via pivoting arm

	attached to surgical bed via articulating arm and bedrail clamp		
Registration Compatibility	Fiducial Registration	NaviLink and Fiducial Registration	Fiducial Registration

G. Performance Testing

Nonclinical testing was performed to demonstrate that the subject device 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.

- Non-clinical system, software, and instrument verification and validation – demonstrated compliance with user needs and corresponding design inputs.
- Qualitative validation to confirm intended use
- Testing was performed to ensure compliance with recognized standards mentioned below for tracking navigation accuracy and usability.
  - ASTM F2554-10: Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems
  - IEC 62366:2020 Medical devices – Part 1: Application of usability engineering to medical devices
  - IEC 62304:2015 Medical device software – Software lifecycle processes

The results of testing 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 device has been shown to be substantially equivalent to legally marketed predicate devices.