January 11, 2026

Alphatec Spine, Inc.
Garima Shrivastava
Senior Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K252842
Trade/Device Name: SafeOp 3: Neural Informatix System
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF, GXY, GXZ, IKN, PDQ, ETN
Dated: December 12, 2025
Received: December 12, 2025

Dear Garima Shrivastava:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

JAY R. GUPTA -S

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252842

Please provide the device trade name(s).

SafeOp 3: Neural Informatix System

Please provide your Indications for Use below.

The SafeOp 3: Neural Informatix System is intended for use in monitoring neurological status by recording transcranial motor evoked potentials (MEP), somatosensory evoked potentials (SSEP), electromyography (EMG), or assessing the neuromuscular junction (NMJ). Neuromonitoring procedures include intracranial, extracranial, intratemporal, extratemporal, neck dissections, upper and lower extremities, spinal degenerative treatments, pedicle screw fixation, intervertebral fusion cages, rhizotomy, orthopedic surgery, open/percutaneous, lumbar, thoracic, and cervical surgical procedures.

SafeOp 3 Accessories: The SafeOp Accessories are utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

A. SUBMITTER:

Alphatec Spine, Inc.
1950 Camino Vida Roble
Carlsbad, CA 92008
Phone: (760) 431-9286
Fax: (760) 431-0289

Contact Person: Garima Shrivastava
Senior Regulatory Affairs Specialist
Alphatec Spine, Inc.
Email: gshrivastava@atecspine.com
Contact Phone: (760) 356-6783

Date Summary Prepared: September 5, 2025

B. DEVICE

Trade or Proprietary Name:	SafeOp 3: Neural Informatix System
Common or Usual Name:	Intraoperative Neuromonitoring
Classification Name:	Stimulator, Electrical, Evoked Response
Regulation Number:	21 CFR 882.1870
Classification:	Class II
Product Codes:	GWF, GXY, GXZ, IKN, PDQ, ETN

C. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate:

510(k)	Product Name	Clearance Date
K234092	SafeOp 3™: Neural Informatix System	04/19/2024

D. DEVICE DESCRIPTION

The SafeOp™ 3: Neural Informatix System (SafeOp 3 System), consists of the SafeOp patient interface with power supply and IV pole mount, the Alpha Informatix Tablet with docking station and power supply and a data transfer USB cable. Associated disposable accessories consists of an electrode harness, surface and/or subdermal needle electrodes, MEP Activator, Cranial Hub, Delta Dilators and Stimulating Probe and Delta Clip contained in various kits.

The subject device is intended for use by trained healthcare professionals, clinical

neurophysiologists/technologists and appropriately trained non-clinical personnel. The subject device is intended for use in operating room environments of hospitals and surgical centers. System setup may be performed by both clinical and trained non-clinical personnel.

The subject device records the following modalities:

- Somatosensory evoked potentials (SSEP)
- Motor evoked potentials (MEP),
- Train-of-four neuromuscular junction (TO4),
- Triggered electromyography (tEMG) and
- Free run electromyography (sEMG)

E. INTENDED USE AND INDICATIONS FOR USE

Intended Use

The SafeOp 3: Neural Informatix System is intended for use by trained healthcare professionals as a diagnostic device that provides intraoperative neuromonitoring during various surgical procedures.

Indications for Use

The SafeOp 3: Neural Informatix System is intended for use in monitoring neurological status by recording transcranial motor evoked potentials (MEP), somatosensory evoked potentials (SSEP), electromyography (EMG), or assessing the neuromuscular junction (NMJ). Neuromonitoring procedures include intracranial, extracranial, intratemporal, extratemporal, neck dissections, upper and lower extremities, spinal degenerative treatments, pedicle screw fixation, intervertebral fusion cages, rhizotomy, orthopedic surgery, open/percutaneous, lumbar, thoracic, and cervical surgical procedures.

SafeOp 3 Accessories: The SafeOp Accessories are utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.

F. TECHNOLOGICAL COMPARISON TO PREDICATES

The subject device was compared to the predicate device in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent. Any technological differences within this 510(k), between the subject device and the predicate device, does not impact substantially equivalence, or safety and effectiveness. ***Table 1*** below provides a detailed analysis of the substantial equivalence of the following device characteristics: indications for use and device functionalities.

Table 1: Comparison for Substantial Equivalence

Specification/Property	Predicate Device	Subject Device	SE Rationale (if not identical)
510(k)	**SafeOp 3: Neural Informatix System (K234092)**	**SafeOp 3: Neural Informatix System**	
Intended Use/ Indications for Use	The SafeOp 3: Neural Informatix System is intended for use by trained healthcare professionals as a diagnostic device that provides intraoperative neuromonitoring during various surgical procedures. The SafeOp 3: Neural Informatix System is intended for use in monitoring neurological status by recording transcranial motor evoked potentials (MEP), somatosensory evoked potentials (SSEP), electromyography (EMG), or assessing the neuromuscular junction (NMJ). Neuromonitoring procedures include intracranial, extracranial, intratemporal, extratemporal, neck dissections, upper and lower extremities, spinal degenerative treatments, pedicle screw fixation, intervertebral fusion cages, rhizotomy, orthopedic surgery, open/percutaneous, lumbar, thoracic, and cervical surgical procedures. **SafeOp 3 Accessories**: The SafeOp Accessories are utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.	The SafeOp 3: Neural Informatix System is intended for use by trained healthcare professionals as a diagnostic device that provides intraoperative neuromonitoring during various surgical procedures. The SafeOp 3: Neural Informatix System is intended for use in monitoring neurological status by recording transcranial motor evoked potentials (MEP), somatosensory evoked potentials (SSEP), electromyography (EMG), or assessing the neuromuscular junction (NMJ). Neuromonitoring procedures include intracranial, extracranial, intratemporal, extratemporal, neck dissections, upper and lower extremities, spinal degenerative treatments, pedicle screw fixation, intervertebral fusion cages, rhizotomy, orthopedic surgery, open/percutaneous, lumbar, thoracic, and cervical surgical procedures. **SafeOp 3 Accessories**: The SafeOp Accessories are utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.	**The indications for use for the subject SafeOp 3 System are identical to the predicate SafeOp 3 System (K234092).**
Device Class	II	II	**Identical to predicate, SafeOp 3 System (K234092)**
Product Code	GWF, GXY, GXZ, IKN, PDQ, ETN	GWF, GXY, GXZ, IKN, PDQ, ETN	**Identical to predicate, SafeOp 3 System (K234092)**
Regulation Number (21 CFR)	§882.1870, §882.1320, §882.1350, §890.1375, §874.1820, §874.1820	§882.1870, §882.1320, §882.1350, §890.1375, §874.1820, §874.1820	**Identical to predicate, SafeOp 3 System (K234092)**
Device Classification Name	Stimulator, Electrical, Evoked Response, Surgical nerve stimulator/locator	Stimulator, Electrical, Evoked Response, Surgical nerve stimulator/locator	**Identical to predicate, SafeOp 3 System (K234092)**
Monitoring Modalities/Operating Modes	• Electrode Test • Electromyography (EMG) • Somatosensory Evoked Potentials (SSEP) • Transcranial Motor Evoked Potential (TcMEP or MEP) • Neuromuscular Junction Testing – Train of Four (TO4)	• Electrode Test • Electromyography (EMG) • Somatosensory Evoked Potentials (SSEP) • Transcranial Motor Evoked Potential (TcMEP or MEP) • Neuromuscular Junction Testing – Train of Four (TO4)	**Identical to predicate, SafeOp 3 System (K234092).**
System Components	• Patient Interface • Tablet • Docking station	• Patient Interface • Tablet • Docking station	**Substantially equivalent to predicate, SafeOp 3 System (K234092).** **The subject device incorporates minor hardware updates to the Patient**

Specification/Property	Predicate Device	Subject Device	SE Rationale (if not identical)
510(k)	**SafeOp 3: Neural Informatix System (K234092)**	**SafeOp 3: Neural Informatix System**	
			Interface and the Tablet that do not alter the device's intended use, technological characteristics, or clinical performance. Performance testing confirmed equivalent performance and no new or increased risks.
60601-1 Compliant	Yes	Yes	**Identical to predicate, SafeOp 3 System (K234092)**
Power Supply	100 to 240 VAC, 50-60 Hz (input); 12 VDC, 2.5 A (output)	100 to 240 VAC, 50-60 Hz (input); 12 VDC, 2.5 A (output)	**Identical to predicate, SafeOp 3 System (K234092)**
Mode of Operation	Continuous	Continuous	**Identical to predicate, SafeOp 3 System (K234092)**
Dimensions	Patient Interface: 14"H. x 8.5"W x 5"D Tablet with Docking Station: 11.5"H x 13.3"W x 6.5"D	Patient Interface: 14"H. x 8.5"W x 5"D Tablet with Docking Station: 11.5"H x 13.3"W x 6.5"D	**Identical to predicate, SafeOp 3 System (K234092)**
Weight	Patient Interface: < 7 lbs Tablet with Docking Station: 5.45 lbs	Patient Interface: < 7 lbs Tablet with Docking Station: 5.45 lbs	**Identical to predicate, SafeOp 3 System (K234092)**
Total Amplifier Channels	Up to 16	Up to 16	**Identical to predicate, SafeOp 3 System (K234092)**
Stim Waveform	Monophasic, Rectangular	Monophasic, Rectangular	**Identical to predicate, SafeOp 3 System (K234092)**
Stim Pulse Duration	100 to 500 µsec (SSEP) 200 µsec (tEMG) 200 to 400 µsec (TO4) 50 to 150 µsec (MEP)	100 to 500 µsec (SSEP) 200 µsec (tEMG) 200 to 400 µsec (TO4) 50 to 150 µsec (MEP)	**Identical to predicate, SafeOp 3 System (K234092)**
Stim Frequency (Pulse Rate)	0.1 to 50 Hz	0.1 to 50 Hz	**Identical to predicate, SafeOp 3 System (K234092).**
Stim Current Range	0 to 100 mA 0 to 1500 mA for MEP only	0 to 100 mA 0 to 1500 mA for MEP only	**Identical to predicate, SafeOp 3 System (K234092).**
Stim Voltage Range	0-1000 V for MEP	0-1000 V for MEP	**Identical to predicate, SafeOp 3 System (K234092).**
Input Impedance	> 50 MΩ	> 50 MΩ	**Identical to predicate, SafeOp 3 System (K234092)**
Low Frequency Filter	1 - 30 Hz	1 - 30 Hz	**Identical to predicate, SafeOp 3 System (K234092).**
High Frequency Filter	1.5 – 3kHz	1.5 – 3kHz	**Identical to predicate, SafeOp 3 System (K234092).**
Operating System	Windows 10 powered tablet	Windows 11 powered tablet	**Substantially equivalent to predicate, SafeOp 3 System (K234092). For more information, see Section-9, Performance Testing.**

Specification/Property	Predicate Device	Subject Device	SE Rationale (if not identical)
510(k)	**SafeOp 3: Neural Informatix System (K234092)**	**SafeOp 3: Neural Informatix System**	
Remote Access	No	No	**Identical to predicate, SafeOp 3 System (K234092).**
Voltage Range	50-1000V	50-1000 V	**Identical to predicate, SafeOp 3 System (K234092).**
Current Range	50 µsec - 500 µsec	50 µsec - 500 µsec	**Identical to predicate, SafeOp 3 System (K234092).**
Impedance Measurement	All outputs	All outputs	**Identical to predicate, SafeOp 3 System (K234092).**
MEP Stim Outputs	Four outputs, arranged in two pairs, polarity selectable	Four outputs, arranged in two pairs, polarity selectable	**Identical to predicate, SafeOp 3 System (K234092).**
MEP Repetition rate	1 Hz	1 Hz	**Identical to predicate, SafeOp 3 System (K234092).**
Maximum energy into 1 kohm impedance	50mJ/pulse	50mJ/pulse	**Identical to predicate, SafeOp 3 System (K234092).**

G. PREDETERMINED CHANGE CONTROL PLAN (PCCP)

The PCCP for the SafeOp 3 System includes the following planned software and algorithmic modifications, which will be implemented under documented design control procedure. Each proposed change will be implemented in accordance with detailed modification protocols and must meet defined performance and safety criteria prior to implementation.

- **Modification #1 - Stimulation site specific SSEP Baseline Classification Algorithm**
  The system's SSEP baseline classification algorithm will be re-trained using site-specific data from the posterior tibial, saphenous, and ulnar nerves. Dedicated classifiers for each stimulation site are expected to improve robustness and performance while maintaining the algorithm's existing inputs, outputs, and intended use. Performance verification will include testing against predefined accuracy, positive predictive value (PPV), and F1-score criteria using an independent, firewalled dataset. The modified SSEP baseline classification algorithm must meet overall PPV $\geq$ 90%, overall accuracy and F1-score $\geq$ 85%. Performance of each stimulation site-specific classifier must be demonstrated to be non-inferior to the current SafeOp 3 System at the 95% confidence level.

- **Modification #2 - Removal of the Recalculating Active Trace (RAT) State**
  The planned modification will remove the RAT state from the SSEP modality. Following restart of SSEP acquisition, new single trials will be incorporated into the existing ensemble average rather than resetting it. Internal testing and retrospective analysis of intraoperative data will be used to confirm non-inferiority in signal quality relative to the current implementation. The average noise content for the reconstructed EA following restart will be demonstrated to be non-inferior to that of the preceding EA(s) with 95% confidence.

- **Modification #3 - tEMG Using Only the SafeOp Delta Stimulating Clip**
  The system will be modified to enable both traditional and Delta triggered EMG (tEMG) functionality using only the SafeOp Delta Stimulating Clip. An impedance-based detection method will determine the type of surgical instrument connected and automatically initiate the appropriate workflow. Verification activities will confirm system behavior, stimulation accuracy, and UI performance across clinical workflows.

- **Modification #4 – Ongoing Maintenance and Update of the SSEP Baseline Classification Algorithm**
  The stimulation site–specific SSEP classifiers may be periodically re-trained as additional labeled data become available. The model type, inputs, outputs, and intended use will remain unchanged, with all configuration parameters constrained to predefined bounded ranges in the PCCP. The frequency of updates is expected to be four releases per year or fewer and will be

implemented under established design-control procedures.-Verification testing will assess accuracy, PPV, and F-1 score using an independent dataset, and validation will confirm non-inferiority to the cleared classifier. The modified SSEP baseline classification algorithm must meet overall PPV ≥ 90%, overall accuracy and F1-score ≥ 85%. Performance of each stimulation site-specific classifier must be demonstrated to be non-inferior to the current SafeOp 3 System at the 95% confidence level.

Additionally, software workflow and system integration testing will be completed for each of the planned modifications described above.

Each planned modification will be executed in accordance with detailed modification protocols defined in the PCCP. All modifications will undergo appropriate verification and validation activities—including performance testing, design verification, and user validation (when applicable)—to confirm compliance with established acceptance criteria. Authorized modifications will be documented in the device's labeling, as applicable. The implementation of the predetermined change control plan demonstrates continued substantial equivalence to the predicate device.

H. PERFORMANCE DATA

Nonclinical performance testing demonstrates that the subject SafeOp 3 System meets the functional, system, and software requirements.

Usability testing was performed to demonstrate that the subject SafeOp 3 System presents no adverse effect within the intended environment, and the subject device was therefore found to be substantially equivalent to the predicate. A use-related risk analysis (URRA) was conducted as part of the usability testing to identify potential use-related hazards and confirm that implemented mitigations reduce residual risks to acceptable levels.

Clinical Information
Determination of substantial equivalence is not based on an assessment of clinical performance data.

I. CONCLUSION

Based upon the information provided in this 510(k) submission, it has been determined that the subject device, SafeOp 3 System, is substantially equivalent to the legally marketed predicate device in regard to indications for use, intended use, design, technology, and performance.