March 9, 2022

Alphatec Spine, Inc.
David Gramse
Sr. Director, Regulatory & Clinical Affairs
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K213849
Trade/Device Name: SafeOp 2: 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 9, 2021
Received: December 10, 2021

Dear David Gramse:

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,

for
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

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)*

Device Name

SafeOp 2: Neural Informatix System

Indications for Use *(Describe)*

The SafeOp 2: Neural Informatix System is intended for use in monitoring neurological status by recording 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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

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

## I. SUBMITTER:

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Phone: (760) 494-6711
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Contact Person: David Gramse
Sr. Director, Regulatory and Clinical Affairs
Alphatec Spine, Inc.
Contact Phone: (760) 494-6711

Date Summary Prepared: December 8, 2021

## II. DEVICE

| | |
|---|---|
| Trade Name: | SafeOp™ 2: Neural Informatix System |
| Common or Usual Name: | Intraoperative Neuromonitoring |
| Classification Name: | Stimulator, Electrical, Evoked Response (21 CFR 882.1870) |
| Regulatory Class: | Class II |
| Product Code: | GWF |
| Subsequent Codes: | GXY, GXZ, IKN, PDQ, ETN |

## III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate:

| 510(k) | Product Name | Clearance Date |
|---|---|---|
| K182542 | EPAD™ 2 System | February 2019 |

## IV. DEVICE DESCRIPTION

The SafeOp™ 2: Neural Informatix System (SafeOp 2 System), formerly known as EPAD 2 (K182542), consists of the SafeOp head unit 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, and stimulating probe or clip contained in various kits.

The SafeOp 2 System head unit contains a complete data acquisition system that has built-in stimulators, amplifiers, relays, A/D Converters, Digital Signal Processors, CPUs, and storage devices. The head unit interfaces with other equipment through communication ports and serves as the patient-contacting portion of the system where it is close to the surgical field. The head unit hardware contains an eight acquisition (input) channel and six-output channel Evoked Potential Stimulator that is used in the operating room to display nerve and muscle responses. The user can use these responses to diagnose insults to the peripheral or central nerves and to determine relative nerve location, proximity, and integrity data.

The SafeOp 2 System application provides the primary graphical user interface and controls for the SafeOp 2 System. The application runs on a touchscreen tablet mobile device which connects to the head unit either via wired USB cable or wireless via Wi-Fi, enabling both user input (e.g., patient and procedure information, adjustment of stimulus and acquisition parameters) and display of output (e.g., display of acquired waveforms, data, messages and alerts to the clinician).

## V. INDICATIONS FOR USE

The SafeOp 2: Neural Informatix System is intended for use in monitoring neurological status by recording 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.

## VI. 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: Comparison for Substantial Equivalence**

| Specification/ Property | Predicate Device | Subject Device | SE Rationale (if not identical) |
|---|---|---|---|
| **510(k)** | **EPAD™ 2 System (K182542)** | **SafeOp™ 2 System** | |
| **Intended Use/ Indications for Use** | The EPAD 2 system is intended for use by trained healthcare professionals as a diagnostic device that provides intraoperative neuromonitoring during various surgical procedures.<br><br>The EPAD 2 system is intended for use in monitoring neurological status by recording 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 or percutaneous, lumbar, thoracic, and cervical surgical procedures. | The SafeOp 2: Neural Informatix System is intended for use by trained healthcare professionals as a diagnostic device that provides intraoperative neuromonitoring during various surgical procedures.<br><br>The SafeOp 2: Neural Informatix System is intended for use in monitoring neurological status by recording 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. | **Identical** |
| **Device Class** | II | II | **Identical** |
| **Product Code** | GWF, GXY, GXZ, IKN, PDQ, ETN | GWF, GXY, GXZ, IKN, PDQ, ETN | **Identical** |
| **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** |

| Specification/ Property | Predicate Device | Subject Device | SE Rationale (if not identical) |
|---|---|---|---|
| **510(k)** | **EPAD™ 2 System (K182542)** | **SafeOp™ 2 System** | |
| **Device Classification Name** | Stimulator, Electrical, Evoked Response | Stimulator, Electrical, Evoked Response | **Identical** |
| **Monitoring Modalities** | Electromyography (EMG)<br>Somatosensory Evoked Potentials (SSEP)<br>Neuromuscular Junction Testing (NMJ) | Electromyography (EMG)<br>Somatosensory Evoked Potentials (SSEP)<br>Neuromuscular Junction Testing (NMJ) | **Identical** |
| **Head Unit Power Supply** | | | |
| **60601-1 Compliant** | Yes | Yes | **Identical** |
| **Head Unit Power Supply** | 100 to 240 VAC, 50-60 Hz (input); 15 VDC, 2.5A (output) | 100 to 240 VAC, 50-60 Hz (input); 12 VDC, 2.5A (output) | Head unit power supply does not impact device performance when compared to the predicate. The change in power does not introduce new risks, or impact existing risks. Therefore, this difference does not affect device safety or effectiveness. |
| **Mode of Operation** | Continuous | Continuous | **Identical** |
| **Dimensions** | 12”W x 8”H x 2”D | 12”W x 8”H x 2”D | **Identical** |
| **Weight** | < 2 lbs | < 2 lbs | **Identical** |
| **Principles of Operation** | | | |
| **Operating Modes** | Triggered EMG<br>Free run EMG<br>SSEP<br>NMJ | Triggered EMG<br>Free run EMG<br>SSEP<br>NMJ | **Identical** |
| **Total Amplifier Channels** | Up to 8 | Up to 8 | **Identical** |

| Specification/ Property | Predicate Device | Subject Device | SE Rationale (if not identical) |
|---|---|---|---|
| **510(k)** | **EPAD™ 2 System (K182542)** | **SafeOp™ 2 System** | |
| **Waveform** | Monophasic, Rectangular | Monophasic, Rectangular | **Identical** |
| **Pulse Duration** | 50 to 300 µsec | 300 µsec (SSEP)<br>200 µsec (EMG) | **Identical** |
| **Frequency (Pulse Rate)** | 0.1 to 50 Hz | 0.1 to 50 Hz | **Identical** |
| **Current Range** | 0 to 100 mA | 0 to 100 mA | **Identical** |
| **Input Impedance** | > 50 MΩ (at DC) | > 50 MΩ (at DC) | **Identical** |
| **Low Frequency Filter** | 10 Hz (SSEP)<br>30 Hz (EMG) | 10 Hz (SSEP)<br>30 Hz (EMG) | **Identical** |
| **High Frequency Filter** | 2.7 kHz (SSEP & EMG) | 2.7 kHz (SSEP & EMG) | **Identical** |
| **Notch Filter** | 50 or 60 Hz | 50 or 60 Hz | **Identical** |
| **AlphaInformatix (AIX) Tablet** | | | |
| **Operating System** | Android powered tablet | Windows 10 powered tablet | Completed V&V testing successfully demonstrates that the differences in the Operating Systems (OS) have no impact on device performance when compared to the predicate. The OS change does not introduce new risks, or impact existing risks. Therefore, this difference does not affect device safety or effectiveness. |
| **Remote Access** | No | No | **Identical** |

| Specification/ Property | Predicate Device | Subject Device | SE Rationale (if not identical) |
|---|---|---|---|
| **510(k)** | **EPAD™ 2 System (K182542)** | **SafeOp™ 2 System** | |
| **Surface Electrodes** | | | |
| **Anatomical Sites** | SSEP: Upper/lower limbs and head/neck | SSEP: Upper/lower limbs and head/neck | **Identical** |
| **Type** | Customer cutaneous electrodes for use with SafeOp only. Single, double and triple electrodes. | Customer cutaneous electrodes for use with SafeOp only. Single, double and triple electrodes. | **Identical** |
| **Conductive Surface Area** | 20x25mm | 25.4x25.4mm (1x1in.) | Completed V&V testing successfully demonstrates that the differences in the surface area has no impact on device performance when compared to the predicate. The change does not introduce new risks, or impact existing risks. Therefore, this difference does not affect device safety or effectiveness. |
| **Conductive Gel** | Wet gel | Solid gel | Completed V&V testing successfully demonstrates that the differences in the conductive gel has no impact on device performance when compared to the predicate. The change does not introduce new risks, or impact existing risks. Therefore, this difference does not affect device safety or effectiveness. |
| **Connectors** | Nicomatic three pin | Nicomatic three pin | **Identical** |
| **Current Density** | < 0.75 $mA_{rms}$/cm2 | < 0.75 $mA_{rms}$/cm2 | **Identical** |
| **Sterility** | Non-sterile, single patient use, disposable | Non-sterile, single patient use, disposable | **Identical** |
| **Surface Contact Time** | ≤ 24 hours | ≤ 24 hours | **Identical** |

| Specification/ Property | Predicate Device | Subject Device | SE Rationale (if not identical) |
|---|---|---|---|
| **510(k)** | **EPAD™ 2 System (K182542)** | **SafeOp™ 2 System** | |
| **Other Accessories** | | | |
| **Needle Electrodes** | Yes | Yes | **Identical** |
| **Stimulating Probes** | Yes | Yes | **Identical** |
| **Cable, Electrode** | Yes | Yes | **Identical** |
| **Biocompatibility of patient contacting accessories (ISO 10993-1)** | Yes<br>Tissue/bone/dentin for a limited duration of less than or equal to 24 hours. | Yes<br>Tissue/bone/dentin for a limited duration of less than or equal to 24 hours. | **Identical** |

## VII. PERFORMANCE DATA

Nonclinical performance testing demonstrates that the subject SafeOp 2 System meets the functional, system, and software requirements.

EMC and Electrical Safety Testing of the SafeOp 2 System was performed to ensure all functions of the system and its accessories are electrically safe, and comply with recognized electrical safety standards

Usability testing was performed to demonstrate that the subject SafeOp 2 System presents no adverse effect within the intended environment, and the subject device was therefore found to be substantially equivalent to the predicate.

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

## VIII. CONCLUSION

Based upon the information provided in this 510(k) submission, it has been determined that the subject device, SafeOp 2 System, is substantially equivalent to the legally marketed primary predicate device in regards to indications for use, intended use, design, technology, and performance.