April 19, 2024

Alphatec Spine, Inc.
Unnati Bhuptani
Sr. Regulatory Affairs Specialist
1950 Camino Vida Roble
Carlsbad, California 92008

Re: K234092
Trade/Device Name: SafeOp 3: Neural Informatix Systeem
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: March 21, 2024
Received: March 21, 2024

Dear Unnati Bhuptani:

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.

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,

FDA Patrick Antkowiak -S

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.

Submission Number *(if known)*

K234092

Device Name

SafeOp 3: Neural Informatix System

Indications for Use *(Describe)*

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.

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 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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Contact Person: Unnati Bhuptani
Sr. Regulatory Affairs Specialist
Alphatec Spine, Inc.
Contact Phone: (760) 356-6711

Date Summary Prepared: March 20, 2024

II. DEVICE

Trade Name:	SafeOp™ 3: 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
K213849	SafeOp2: Neural Informatix System	March 9, 2022

IV. 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, PMAP Dilators and stimulating probe or 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)

V. 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.

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	Reference Device		Primary Predicate Device	Subject Device	SE Rationale (if not identical)
510(k)	**Cascade IOMAX Intraoperative Monitor (K162199)**	**ATEC IOM Accessory Instruments (K221821)**	**SafeOp 2: Neural Informatix System (K213849)**	**SafeOp 3: Neural Informatix System**	
Intended Use/ Indications for Use	The Cascade IOMAX™ Intraoperative Monitor with Surgical Studio software (IOMAX) is an electroneurodiagnostic device that acquires, displays and stores physiologic data from peripheral sensory and motor nerves, muscles and the central nervous system, generated either spontaneously or elicited by well-defined stimuli. The acquired data are necessary to perform somatosensory, auditory and visual evoked potentials (EPs), electroencephalography (EEG), electromyography (EMG), transcranial motor evoked potentials (TcMEPs), direct cortical stimulation, nerve conduction studies and Train of Four (TOF) analysis. SpO2 measures and displays oxygen saturation and heart rate information. The system also delivers direct nerve stimulation required for specific surgical procedures. Evoked Potentials (EPs): IOMAX provides electrical, auditory or visual stimulation and measures, displays, records, and stores the electrical activity of the nervous system in response to the stimulation. EEG: IOMAX measures, displays, records, and stores electrical activity of the brain from two or more electrodes on the head. Free Run EMG: IOMAX acquires, displays, records, and stores spontaneous EMG activity of motor nerves by continually displaying a live	The ATEC IOM Accessory Instruments 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.	**Intended use** 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. **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.	**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.	**Same as predicates and reference devices**

Specification/ Property	Reference Device		Primary Predicate Device	Subject Device	SE Rationale (if not identical)
510(k)	Cascade IOMAX Intraoperative Monitor (K162199)	ATEC IOM Accessory Instruments (K221821)	SafeOp 2: Neural Informatix System (K213849)	SafeOp 3: Neural Informatix System	
	stream of mechanically induced myotome contractions. TcMEP: IOMAX delivers transcranial stimulation via dedicated outputs for intraoperative assessment. Cortical Stimulation: IOMAX delivers Low Current Stimulation (LCS) during surgical procedures to map various areas of the cortex. Triggered EMG (TEMG): IOMAX electrically stimulates the motor nerves, and displays, records, and stores the resulting compound muscle action potentials in the innervated muscle. Nerve Conduction Study (NCS): IOMAX measures, displays, records, and stores sensory and motor nerve conduction time (latency) by applying a stimulus to peripheral nerves, the spinal cord, and the central nervous system. Train of Four (TOF) or Twitch Test: IOMAX delivers a train of four pulses and measures, displays, records, and stores the compound muscle action potential amplitude fade for analysis. SpO2: IOMAX measures and displays oxygen saturation and heart rate information. Remote Reader: IOMAX provides passive, real time remote review of intraoperative monitoring for a physician outside of the operating room. IOMAX is used by or under the direction of a licensed physician, surgeon, or neurologist in a professional healthcare facility environment for				

Specification/ Property	Reference Device		Primary Predicate Device	Subject Device	SE Rationale (if not identical)
510(k)	**Cascade IOMAX Intraoperative Monitor (K162199)**	**ATEC IOM Accessory Instruments (K221821)**	**SafeOp 2: Neural Informatix System (K213849)**	**SafeOp 3: Neural Informatix System**	
	pre-operative, intraoperative and post-operative testing.				
Device Class	II	II	II	II	**Identical to predicate and reference devices**
Product Code	GWF, DQA, ETN, GWE, GWJ, GWQ, GZO, IKN, JXE, OLT	PDQ, ETN	GWF, GXY, GXZ, IKN, PDQ, ETN	GWF, GXY, GXZ, IKN, PDQ, ETN	**Identical to predicate and reference devices**
Regulation Number (21 CFR)	§882.1870, §870.2700, §874.1820, §882.1890, §882.1900, §882.1400, §882.1540, §890.1375, §882.1550	§874.1820	§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 and reference devices**
Device Classification Name	Stimulator, Electrical, Evoked Response	Surgical nerve stimulator/locator	Stimulator, Electrical, Evoked Response	Stimulator, Electrical, Evoked Response, Surgical nerve stimulator/locator	**Identical to predicate and reference devices**

Monitoring Modalities/Operating Modes	• Electrode Impedance Test
	• Evoked potential (EP) in the form of:
	  ○ Brainstem auditory
	  ○ Visual
	  ○ Somatosensory
	• Transcranial electrical motor evoked potential (TcMEP)
	• Electromyography (EMG)
	• Electroencephalogram (EEG)
	• Nerve conduction studies in the form of:
	  ○ NCV
	  ○ F wave
	  ○ H reflex
	  ○ Train of four (TOF)
	• SpO2 and heart rate values
		N/A	• Electrode Test
			• Electromyography (EMG)
			• Somatosensory Evoked Potentials (SSEP)
			• Neuromuscular Junction Testing – Train of Four (TO4)
				• Electrode Test
				• Electromyography (EMG)
				• Somatosensory Evoked Potentials (SSEP)
				• Motor Evoked Potential (TcMEP or MEP)
				• Neuromuscular Junction Testing – Train of Four (TO4)
					Identical to predicate and reference devices

Specification/ Property	Reference Device		Primary Predicate Device	Subject Device	SE Rationale (if not identical)
510(k)	**Cascade IOMAX Intraoperative Monitor (K162199)**	**ATEC IOM Accessory Instruments (K221821)**	**SafeOp 2: Neural Informatix System (K213849)**	**SafeOp 3: Neural Informatix System**	
	• Threshold mode				
60601-1 Compliant	Yes	N/A	Yes	Yes	**Identical to predicate and reference devices**
Total Amplifier Channels	Supports Up to 48	N/A	Up to 8	Up to 16	**Substantially Equivalent to the predicates and reference device**
Operating System	Windows 7 Professional (SP1, 64-bit) or Windows 10. Windows 10	N/A	Windows 10 powered tablet	Windows 10 powered tablet	**Identical to predicate, SafeOp 2 System (K213849)**
Remote Access	No	N/A	No	No	**Identical to predicate and reference devices**

B. Discussion of the MEP modality

Motor Evoked Potentials (MEP) is a neuromonitoring modality commonly used in surgical procedures to periodically assess the integrity of motor neural function and identify any significant changes during surgery. The MEP modality has been added to the subject SafeOp 3 System to provide this additional monitoring modality to ensure integrity of descending motor tracts and support the standard practice of 'multi-modality' monitoring which provides assessment of both ascending (sensory) and descending (motor) spinal pathways.

Comparison to MEP functionality in the reference device, Cascade IOMAX Intraoperative System (K162199):

The reference device provides a wide range of neuromonitoring capabilities such as somatosensory, auditory and visual evoked potentials (EPs), electroencephalography (EEG), electromyography (EMG), transcranial motor evoked potentials (TcMEPs), direct cortical stimulation, nerve conduction studies and Train of Four (TOF) analysis. Since the subject SafeOp 3 System is simplified and focused on spinal neuromonitoring applications specifically, the capabilities of the subject SafeOp 3 System for the MEP modality are a subset of the reference device, Cascade IOMAX Intraoperative Monitor (K162199). The limited stimulation and acquisition parameters of the subject SafeOp 3 System exist as a subset of the reference device, Cascade IOMAX Intraoperative Monitor's (K162199) specification range to best serve the intended use of spinal neuromonitoring. ***Table 2*** below provides a detailed comparison of technological characteristics between the subject SafeOp 3 System and reference device, Cascade IOMAX Intraoperative Monitor (K162199) specific to the MEP modality. The comparison provided in ***Table 2*** demonstrates that the MEP modality of the subject SafeOp 3 System can be considered substantially equivalent to the reference device, Cascade IOMAX Intraoperative Monitor (K162199).

Table 2: Comparison of Technological Characteristics

Feature	Cascade IOMAX Intraoperative Monitor (K162199)	SafeOp 3 System (subject device)	Comparison	Substantial Equivalence Rationale
MEP Stim outputs	Nine outputs, each selectable as anode or cathode	Four outputs, arranged in two pairs, polarity selectable	The subject SafeOp 3 System has a defined quadripolar stim montage which is accommodated with the four outputs arranged in two pairs. The MEP Stim Outputs are used to deliver stimulation to the motor cortex via four transcranial electrodes. Bipolar stim montage has traditionally been used to induce a response for MEP stimulation but quadripolar stimulation is also commonly used because of less patient movement and increased likelihood of evoking motor response at lower stimulation levels[1]. The SafeOp 3 System used a quadripolar stim montage to elicit a response at lower stimulation levels.	• Testing which covers the system level delivery of MEP Pulses as set by the user, across the settable range of pulse configurations. • Testing which covers the acquisition sensitivity of MEP Responses across all available channels • Testing which covers firmware MEP stimulation energy limits and stimulation diagnostics The above listed system level and firmware level testing demonstrate that the specifications have been met through V&V Testing individually and as part of the system, no significant failures or deviations were observed.
Total Amplifier Channels	Up to 48	Up to 16	The subject SafeOp 3 System is specific for use in spine. The system utilizes the 16 amplifier channels in the following manner: - 6 bilateral channels for EMG acquisition (12 total, leveraged by the Train of Four, sEMG, tEMG, and MEP Modalities). This supports adequate coverage for the monitoring modalities stated above and case types supported. - 3 channels for SSEP acquisition. This supports cortical and trans-cortical SSEP acquisition montages, which is adequate coverage for the monitoring modalities and case types supported. - 1 extra channel for either EMG of SSEP acquisition. Since the reference device Cascade IOMAX Intraoperative Monitor (K162199) is used in neuromonitoring applications in addition to spine, the reference device requires additional channels to perform other neuromonitoring activities such as EEG. As described above, the subject SafeOp 3 System only requires 16 amplifier channels to perform neuromonitoring for all modalities. Therefore, the differences in number	

[1] Schwartz, SL., et.al, (2022). "Quadripolar" Transcranial Electrical Stimulation for Motor Evoked Potentials. *J Clinl Neurophysiology,* 39(1), 92-97. doi: 10.1097/WNP.0000000000000751.

Feature	Cascade IOMAX Intraoperative Monitor (K162199)	SafeOp 3 System (subject device)	Comparison	Substantial Equivalence Rationale
			of amplifier channels does not affect the subject SafeOp 3 System's ability to perform as intended or safety and effectiveness of the device.	Completed V&V testing successfully demonstrates that the differences in the technological characteristics have no impact on the performance, safety and effectiveness of the subject SafeOp 3 System when compared to the reference device, Cascade IOMAX Intraoperative Monitor (K162199). The differences in the technological characteristics between subject SafeOp 3 System and the reference device, Cascade IOMAX Intraoperative Monitor (K162199) do not introduce any new risks that are not already inherent to clinical use of the MEP Modality. All risks related to the addition of the MEP Modality have been adequately mitigated. Therefore, these differences in technological characteristics do not affect device safety or effectiveness and can be considered Substantially Equivalent to the reference device Cascade IOMAX Intraoperative Monitor (K162199).
Stim Waveform	Positive, Negative, Biphasic	Positive, Negative	The reference device, Cascade IOMAX Intraoperative Monitor (K162199) uses optional biphasic stim waveforms for MEPs to limit stimulus artifact with longer pulse durations. The subject SafeOp 3 System has a shorter pulse duration and therefore does not need biphasic waveforms for the MEP modality of the SafeOp 3 System to function as intended.	
Voltage Range	50-1000 V	50-1000 V	Same range as the reference device, Cascade IOMAX Intraoperative Monitor (K162199)	
Current Range	50-1500 mA	50-1500 mA	Same range as the reference device, Cascade IOMAX Intraoperative Monitor (K162199)	
Output Control Mode	Constant voltage or constant current	Constant voltage	the subject SafeOp 3 can be considered substantially equivalent to the reference device, Cascade IOMAX Intraoperative Monitor (K162199), since both systems provide the constant voltage as an output control mode. The Constant Voltage output control mode is most commonly used in intraoperative MEP monitoring according to MacDonald, D.B., et al[2], and therefore was chosen as the preferred Output Control Mode for the subject SafeOp 3 System.	
Pulse Duration	50 µsec - 500 µsec	50 µsec - 150 µsec	The pulse duration required to evoke a motor response is 50µsec. The subject SafeOp 3 System has pulse duration range from 50µsec to 150µsec to provide the user with flexibility in parameters to optimize the likelihood of evoking a response. In addition, since the subject SafeOp3 System uses a quadripolar montage, a motor response can be evoked at the range specified for the subject device. The SafeOp 3 System uses a subset of the Cascade IOMAX Intraoperative Monitor that is generally used in clinical practice. Verification and Validation testing demonstrate that the MEP modality of the SafeOp 3 System functions as intended.	
Maximum energy into 1 kohm impedance	50 mJ/pulse	50 mJ/pulse	Same as the reference Cascade IOMAX Intraoperative Monitor.	
Repetition rate	1 Hz max	1 Hz max	Same	
Low Frequency Filter	0.3 Hz-100 Hz	1-30Hz	The low frequency filter range of 1-30 Hz for the subject SafeOp 3 System is the same as the predicate SafeOp 2 System. This frequency range allows the signal of interest to pass through the filter. Addition of MEP modality does not affect the frequency range of signal of interest. MacDonald, DB, et al[2], found that filter settings of 10–100 Hz to 1500–3000 Hz are appropriate for limb muscles. Stimulus artifact may obscure cranial MEPs with these settings; opening the low frequency filter to 0.2–	

[2] MacDonald DB, et al, (2013). Intraoperative motor evoked potential monitoring – A position statement by the American Society of Neurophysiological Monitoring. *International Federation of Clinical Neurophysiology,* 124(12), 2291-2316. https://doi.org/10.1016/j.clinph.2013.07.025

Feature	Cascade IOMAX Intraoperative Monitor (K162199)	SafeOp 3 System (subject device)	Comparison	Substantial Equivalence Rationale
			2 Hz or constraining it to 150–300 Hz can help. Therefore, although the subject SafeOp 3 System has a smaller low frequency filter range as compared to reference Cascade IOMAX Intraoperative Monitor (K162199), the differences in the range do not affect the safety or effectiveness of the device or its ability to function as intended.	
High Frequency Filter	30Hz – 5kHz	1.5 – 3kHz	The high frequency filter range of 1.5 – 3kHz for the subject SafeOp 3 System is the same as the predicate SafeOp 2 System. This frequency range allows the signal of interest to pass through the filter. Addition of MEP modality has does not affect the frequency range of signal of interest. MacDonald, DB, et al[2], found that filter settings of 10–100 Hz to 1500–3000 Hz are appropriate for limb muscles. Therefore, although the subject SafeOp 3 System has a smaller high frequency filter range as compared to reference Cascade IOMAX Intraoperative Monitor (K162199), the differences in the range do not affect the safety or effectiveness of the device or its ability to function as intended.	
Impedance Measurement	All outputs	All outputs	Same	

VII. PERFORMANCE DATA

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

EMC and Electrical Safety Testing of the SafeOp 3 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 3 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 3 System, is substantially equivalent to the legally marketed primary predicate device in regards to indications for use, intended use, design, technology, and performance.