February 22, 2019

SafeOp Surgical, Inc.
% Jeremy Markovich
Senior Manager, Regulatory and Clinical Affairs
Alphatec Spine, Inc.
5818 El Camino Real
Carlsnad, California 92008

Re: K182542
Trade/Device Name: The EPAD 2 System
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, PDQ, GXY, GXZ, ETN, IKN
Dated: September 14, 2018
Received: September 17, 2018

Dear Jeremy Markovich:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182542

Device Name
EPAD 2 System

Indications for Use *(Describe)*
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.

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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"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:**

SafeOp Surgical, Inc.
11350 McCormick Rd, Suite 1003
Hunt Valley, MD 21031
(410) 891-5708

Contact Person: Jeremy Markovich
Senior Manager, Regulatory and Clinical Affairs
Alphatec Spine, Inc.
Contact Phone: (760) 431-9286

Date Summary Prepared: January 23, 2019

II. DEVICE

Trade or Proprietary Name:	EPAD™ 2 System
Common Name:	Evoked Response Electrical Stimulator
Classification Name:	Evoked Response Electrical Stimulator
Regulation Number:	21 CFR 882.1870
Classification:	Class II
Product Code:	GWF
Subsequent Code:	GXY, GXZ, PDQ, ETN, IKN

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate:

510(k)	Product Name	Clearance Date
K132616	EPAD™ (Evoked Potential Assessing Device)	January 24, 2014

Additional Predicates:

510(k)	Product Name	Clearance Date
K083124	Nerve Integrity Monitor 3.0	February 27, 2009
K061639	Eclipse TCD Neurovascular Workstation Eclipse Neurological Workstation with TCD and vascular Doppler CardioMon	November 1, 2006
K110410	MS-120BK Electric Stimulator Extension Unit	August 4, 2011
K162383	Cadwell Sierra Summit	March 1, 2017

IV. DEVICE DESCRIPTION

The EPAD 2 System consists of the EPAD 2 Headbox and power supply, a tablet computer, electrodes, stimulating probe or clip and cables. The Headbox is responsible for the stimulation and acquisition of signals for the intraoperative neurophysiologic monitoring (IONM) functions. The Headbox contains onboard firmware and is mounted on the operating room (OR) bed by clipping it to the bed side bar. The EPAD application provides the primary graphical user interface and controls for the EPAD II System. The application runs on a touchscreen tablet mobile device which connects wirelessly or via a wired USB cable to the Headbox. The application serves as the interface to the EPAD Headbox, 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 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.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The modified design of the subject device was compared to the predicates in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent. The technological differences within this 510(k) that were shown to be substantially equivalent to the predicates including the addition of an EMG modality.

Table 1: Comparison for Substantial Equivalence

Characteristic	Predicate Devices					Subject Device
510(k)	**Nerve Integrity Monitor 3.0 (K083124)**	**Eclipse TCD Neurovascular Workstation Eclipse Neurological Workstation with TCD and vascular Doppler CardioMon (K061639)**	**MS-120BK Electric Stimulator Extension Unit (K110410)**	**Cadwell Sierra Summit (K162383)**	**EPAD (K132616)**	**EPAD 2 System (K182542)**
Manufacturer	Medtronic Xomed, Inc.	Medtronic Xomed, Inc. (formerly Axon Systems Inc.)	NIHON KOHDEN CORP.	Cadwell Industries, Inc.	SafeOp Surgical, Inc.	SafeOp Surgical, Inc. a subsidiary of Alphatec Holdings, Inc.
Intended Use/ Indications for Use	Intended Use: The NIM 3.0 is intended for locating and identifying cranial and peripheral motor and mixed motor-sensory nerves during surgery, including spinal cord and spinal cord nerve roots. The APS electrode is an accessory intended for providing automatic periodic stimulation to nerves when used with the Medtronic Nerve Monitoring Systems.	The systems are intended for use to monitor sensory and motor pathways and to provide information to determine the state of blood flow in the intracranial and extracranial vascular arteries in adults. The instrument uses electroencephalography (EEG), electromyography (EMG), motor and sensory evoked potentials and nerve potentials and Doppler analysis. Transcranial stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal	When the Low output is selected the MS-120BK is used as a nerve stimulator for surgical procedures and brain mapping during treatment of patients with seizure disorders. When High output is selected the MS-12OBK is used for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency. The system is intended for use by qualified medical personnel within a hospital	Cadwell Sierra Summit: Cadwell Sierra Summit is indicated for acquisition, display, storage, transmission, analysis, and reporting of electrophysiological and environmental data including Electromyography (EMG), Nerve Conduction Studies (NCS), Evoked Potentials (EP), and Autonomic Reponses (RR Interval Variability). The Cadwell Sierra Summit is used to detect the physiologic function of the nervous system, and to support the diagnosis of	The EPAD is intended for use in monitoring neurological status by recording somatosensory evoked potentials (SSEP) or assessing the neuromuscular junction (NMJ).	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

	Indications for NIM 3.0 EMG Monitoring Procedures include: Intracranial, Extracranial, Intratemporal, Extratemporal, Neck Dissections, Thoracic Surgeries, and Upper and Lower Extremities. Indications for Spinal procedures which may use NIM 3.0 EMG monitoring include: Degenerative Treatments, Pedicle Screw Procedures, Fusion Cages, Rhizotomy, Orthopedic Surgery, Open and Percutaneous Lumbar and Cervical Surgical Procedures, and Thoracic Surgical Procedures.	conduction of the corticospinal tract. The system is used in the operating room and critical care areas to provide health care professionals with information to guide surgery and to assess a patient's neurological and vascular status. Doppler analysis is not to be used for Obstetrics.	or clinical environment. The stimulator is available for use on any patients as determined by the qualified medical personnel.	neuromuscular diseases or conditions. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the peripheral nerve; Electromyography measures the electrical activity of the muscle, and Evoked Potentials measure the electrical activity from the central nervous system. The interface for third-party non-invasive imaging display and control is used to visualize the morphology and location of nerves and muscles, and serves as an aid in confirming the results of the aforementioned modalities. Cadwell Sierra Summit is indicated for use by qualified medical practitioners. This device does not provide any diagnostic conclusion about the patient's condition to the user.		percutaneous, lumbar, thoracic, and cervical surgical procedures.

Regulatory Class/Code	Class II GWF, ETN (882.1870)	Class II GWO, GWS, GWF, GWVE, GWVJ, IKN, IYN, ITX (882.1870)	Class II GYC, GWF (882.1310)	Class II IKN, GWF, JXE, GWJ, GWE, GZP (890.1375)	Class II GWF, GXY, IKN (882.1870)	Class II GWF, GXY, GXZ, PDQ, ETN, IKN (882.1870)
60601-1 Compliant	Yes	Yes	Yes	Yes	Yes	Yes
Operating Modes	Triggered EMG Free run EMG	Triggered EMG Free run EMG Evoked Potentials	When connect to the Neuromaster, the extension unit can output high or low current pulses to measure evoked potentials: (e.g., EEG, EMG, MEP, and SSEP)	Triggered EMG Free run EMG Evoked Potentials	SSEP NMJ	Triggered EMG Free run EMG SSEP NMJ
Total Amplifier Channels	1 to 8	Up to 8	16 and 32 when connected to the MEE 1000A through the JB116BK or JB-132BK amplifier	1 to 12	Up to 8	Up to 8
Waveform	Monophasic, Rectangular	Biphasic	Multiphasic, Rectangular	Biphasic	Monophasic, Rectangular	Monophasic, Rectangular
Pulse Width	50 to 250 µsec	50 to 500 µsec	0.05 msec to 0.3 msec per phase (50 to 300 µsec)	0.05 to 1 ms (50 to 1000 µsec)	50 to 300 µsec	50 to 300 µsec
Frequency (Pulse Rate)	1 to 10 Hz	Unknown	0.1 to 50 Hz	Up to 50 Hz	0.1 to 50 Hz	0.1 to 50 Hz

Current Range	0.01 to 30 mA	Unknown	0 to 15 mA	0 to 100 mA	0 to 100 mA	0 to 100 mA
Maximum Current Density	Unknown	Unknown	46 mA RMS/cm^2 smallest electrode conductive surface area = 0.04 cm^2	Unknown	0.75 mA RMS/cm^2 smallest electrode conductive surface area = 2 cm^2	23.6 mA RMS/cm^2 smallest electrode conductive surface area = 0.0816 cm^2
Compatible Accessories	Surface Electrodes Needle Electrodes Stimulating Probes Cable, Electrode	Surface Electrodes Needle Electrodes Stimulating Probes Cable, Electrode	Surface Electrodes Needle Electrodes Cable, Electrode	Surface Electrodes Needle Electrodes Cable, Electrode	Surface Electrodes Needle Electrodes Cable, Electrode	Surface Electrodes Needle Electrodes Stimulating Probes Cable, Electrode
Biocompatibility of patient contacting accessories (ISO 10993-1)	Yes Tissue/bone/dentin for a limited duration of less than or equal to 24 hours.	Unknown	Unknown	Unknown	Yes Tissue/bone/dentin for a limited duration of less than or equal to 24 hours.	Yes Tissue/bone/dentin for a limited duration of less than or equal to 24 hours.

VII. PERFORMANCE DATA

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

EMC and Electrical Safety Testing of the *EPAD 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 *EPAD 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
Not applicable; 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 devices are substantially equivalent to legally marketed devices in regards to indications for use, intended use, design, technology, and performance.