JAN 2 4 2014

4.1	**Date Prepared**	January 23, 2014
4.2	**Contact Person**	Curt LaBelle, MD CEO, SafeOp Surgical, Inc. T: (203) 629-8700 Curt@Safeopsurgical.com
4.3	**Device Trade Name**	EPAD™ (Evoked Potential Assessing Device).
4.4	**Classification Name and Regulation**	Evoked Response Electrical Stimulator 21 CFR 882.1870, GWF, Class II
4.5	**Device Manufacturer**	SafeOp Surgical, Inc. 263 Tresser Blvd Stamford, CT 06901
4.6	**Predicate Device(s)**	Protektor 32, K093304 NeuroEPG, K123843

4.7 Indications for Use

The EPAD is intended for use in monitoring neurological status by recording somatosensory evoked potentials (SSEP) or assessing the neuromuscular junction (NMJ).

4.8 Summary Device Description

The EPAD system consists of the following components/accessories:

EPAD Headbox
EPAD Headbox Power Supply
EPAD Tablet Computer (includes power supply and USB cable)
Stimulator Left Blue Cable Assembly (110 inches)
Stimulator Right Yellow Cable Assembly (110 inches)
Acquisition Left Red Cable Assembly (91 inches)
Acquisition Right White Cable Assembly (92 inches)
Stimulator Left Blue Short Cable Assembly (67 inches)
Stimulator Right Yellow Short Cable Assembly (67 inches)
Acquisition Left Red Short Cable Assembly (44 inches)

Acquisition Right White Short Cable Assembly (72 inches)
Adapter Cable for EPAD Headbox (for leakage current testing)
Upper Limb Electrodes package
Lower Limb Electrodes package

The EPAD Headbox contains a complete data acquisition system that has built-in amplifiers, analog to digital converters, and digital signal processors. User interface is via tablet touchscreen computer provided with the EPAD System and running the Android operating system. The EPAD software application is preloaded onto the tablet. Data can be transferred to an external computer for archiving purposes. Communication between the EPAD Headbox and tablet is via Bluetooth wireless or USB connection.

Electrode cables are provided for left and right stimulation and left and right acquisition, color coded for correct connection to the EPAD Headbox: Custom cutaneous electrodes for stimulus and acquisition are provided by SafeOp for use with the EPAD. A total of 11 electrodes are applied for full patient monitoring (upper and lower limbs). The SafeOp electrodes are wet gel, single patient use, disposable, and biocompatible for short term (<24 hours) use on intact skin.

4.8 Technological Comparison to Predicate Device

The following table provides a detailed side-by-side comparison of technical characteristics of the proposed device to the named predicate devices. The table also includes a discussion of each difference and justification for substantial equivalence.

Category	Proposed SafeOp EPAD™	Predicate Protektor 32 (K093304)*	Predicate NeuroEPG (K123843)**	Discussion of Differences & Justification for SE
Indications for use	Intended for use in monitoring neurological status by recording somatosensory evoked potentials (SSEP) or assessing the neuromuscular junction (NMJ).	Intended for intra-operative neurological monitoring and for assessing acute dysfunction in corticospinal axonal conduction. The instrument uses EEG, EP, EMG and Transcranial Stimulation techniques to provide healthcare professionals with information to help assess a patient's neurological status during surgery.	To objectively record evoked responses from patients 18 years of age and older upon the presentation of sensory stimuli. The product is indicated for use as a diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory) and in surgical procedures for intraoperative monitoring.	Some differences in wording but all three devices are intended to record evoked responses for neurological monitoring. The EPAD is specifically designed for monitoring peripheral SSEPs and NMJ assessment.
General Specifications				
Operating modes	SSEP, NMJ	SSEP, BAEP, AEP, VEP, EEG, TcMEP, EMG	SSEP, AEP	EPAD modes are a subset of the modes offered by the Protektor.
Microprocessor controlled	Yes	Yes	Yes	No difference

Category	Proposed SafeOp EPAD™	Predicate Protektor 32 (K093304)*	Predicate NeuroEPG (K123843)**	Discussion of Differences & Justification for SE
User interface	Tablet (Google Nexus 7)	Laptop or desktop PC	PC	Alternate I/O technology: touchpad tablet vs keyboard computer. Hardware and software testing presented in 510(k) demonstrate safety, effectiveness and SE.
Operating System	Google Android	Windows XP	Microsoft Windows (2000 or XP)	Alternate operating system. Android OS validated for EPAD as part of software V&V.
Interface connection	Bluetooth or USB	USB	USB	Alternate communication protocol. Compliance with FDA guidance for RF Wireless Technology in Medical Devices and applicable FCC regulations.
Power supply	100 to 240 VAC, 50-60 Hz (input); 15 VDC, 1.6A (output)	90 to 264 VAC, 47–63 Hz	Not stated	No difference

Category	Proposed SafeOp EPAD™	Predicate Protektor 32 (K093304)*	Predicate NeuroEPG (K123843)**	Discussion of Differences & Justification for SE
Power consumption	< 24 W	60 W	Not stated	EPAD has lower power consumption due to fewer electronics, i.e., fewer stimulator and acquisition channels and no auditory or visual stimulator circuitry.
Operating environment	Temperature: 10° to 40°C (max 35°C for Tablet and power supply) Relative Humidity: 30%–75%	Temperature: 10°C to 40°C Relative humidity: 30%–75%	Not stated	No difference
Dimensions	Headbox: 8"H x 12"W x 2"D (20.3cm x 30.5cm x 5.1cm) Tablet: 7.8" x 4.7" x 0.4" (19.9cm x 12cm x 1 cm)	Isolation Box: 1.5"H x 3.8"W x 5.0"D (3.8cm x 9.6cm x 12.7cm) Acquisition Box: 5.5"H x 10"W x 8.5"D (14cm x 25.4cm x 21.6cm) Stimulator Box: 5.5"H x 10"W x 8.5"D (14cm x 25.4cm x 21.6cm)	Not stated	Physical size difference due to different design. EPAD acquisition, stimulation and isolation are combined within the Headbox.
Weight	Headbox: < 2 lbs Tablet: < 1 lb	Not stated	Not stated	Cannot compare, weight not stated for predicates.

Category	Proposed SafeOp EPAD™	Predicate Protektor 32 (K093304)*	Predicate NeuroEPG (K123843)**	Discussion of Differences & Justification for SE
Safety features				
Electrocautery detection	Yes	Yes	Not stated	No difference
Patient isolation	Type BF (IEC 60601-1) Isolation amplifiers within EPAD Headbox	Type BF (IEC 60601-1) Separate isolation box	Type BF (IEC 60601-1) Fiber optic signal link	No difference
Stimulus (for peripheral nerve stimulation modes only)				
Number of stimulator channels	Up to 6	Up to 16	Not stated	Fewer stimulus channels needed for EPAD due to fewer operating modes.
Trigger in/out	No, stimulus and acquisition both handled via EPAD; no support for external stimulators	Yes, TTL pulse through BNC connector	Not stated	Trigger in/out not needed for EPAD because EPAD does not support external stimulators.
Stimulus type	Constant current	Constant current	Constant current	No difference
Stimulus intensity level(s)	0 to 100 mA	0 to 100 mA	Current: 0 to 25 mA Voltage: 0 to 50 V Continuously adjustable level with user selectable maximum range into a 2KΩ load)	No difference from Protektor.

Category	Proposed SafeOp EPAD™	Predicate Protektor 32 (K093304)*	Predicate NeuroEPG (K123843)**	Discussion of Differences & Justification for SE
Max voltage	380 VDC with 3.8 kΩ load impedance	400 VDC with 4 kΩ load impedance	Not stated	Slightly lower maximum driving voltage but same expected maximum current.
Pulse duration (pulse width)	Choose from 0.1, 0.2 or 0.3 msec settings	Choose from 0.05, 0.1,.0.2, 0.5 and 1.0 msec settings	10 µsec to 1 msec	EPAD pulse durations are within those offered by predicates, appropriate for EPAD modes.
Repetition rate	0.1 to 50 Hz	0.3 to 1000 Hz	0.1 to 100 Hz	EPAD frequencies are within those offered by predicates, appropriate for EPAD modes.
Stim output indicator	Yes – Amber LED	Yes – Amber LED	Not stated	No difference

Category	Proposed SafeOp EPAD™	Predicate Protektor 32 (K093304)*	Predicate NeuroEPG (K123843)**	Discussion of Differences & Justification for SE
Waveform Acquisition				
Number of acquisition channels	Up to 8, 6 currently active	32	Not stated	Fewer acquisition channels needed for EPAD due to fewer operating modes/electrodes.
Waveform display	Yes	Yes	Yes	No difference
Timebase	2 ms/division to 10 ms/division	0.5 ms/division to 500 ms/division	Not stated	Timebase range for EPAD waveforms is within that offered by predicates, appropriate for EPAD modes.
Sensitivity	0.5 µV/division to 20 µV/division	0.1 µV/division to 5 mV/division	Not stated	EPAD sensitivity range is within that offered by predicates, appropriate for EPAD modes.
Rejection	Independent rejection for each channel plus cautery detection ground lead	Independent rejection for each channel	Yes, artifact rejection threshold of 25 µV	No difference
Input Impedance	>50 MΩ	>50 MΩ	Not stated	No difference
Common mode rejection ratio (CMRR)	>93 dB	>93 dB	Not stated	No difference

Category	Proposed SafeOp EPAD™	Predicate Protektor 32 (K093304)*	Predicate NeuroEPG (K123843)**	Discussion of Differences & Justification for SE
Low frequency filter	0.1 Hz to 500 Hz	0.1 Hz to 500 Hz	Not stated	No difference
High frequency filter	30 Hz to 3 kHz	30 Hz to 15 kHz	Not stated	The Protektor is a general purpose device with broad neurological monitoring modes. As such it is capable of acquiring signals using high frequency filters (HFF) up to 15 kHz. The SSEP and NMJ tests of the EPAD only require a HFF of 3 kHz.
Notch filter	50 or 60 Hz	50 or 60 Hz	Not stated	No difference
Noise level	< 20nV/√Hz	< 20nV/√Hz	Not stated	No difference
Electrodes				
Anatomical sites	SSEP: Upper/lower limbs and head/neck	SSEP: Upper/lower limbs and head/neck AEP: Head	SSEP: Upper/lower limbs and head/neck AEP: Head	EPAD electrodes are appropriate for peripheral nerve monitoring
Type	Custom cutaneous electrodes for use with EPAD only Single, double and triple electrodes	Any standard surface or needle electrodes with standard lead wire	Custom cutaneous electrodes for use with NeuroEPG only Multiple electrode configurations available	EPAD electrodes meet functional test requirements per AAMI/ANSI EC12:2000: Disposable ECG Electrodes

Category	Proposed SafeOp EPAD™	Predicate Protektor 32 (K093304)*	Predicate NeuroEPG (K123843)**	Discussion of Differences & Justification for SE
Conductive gel	Wet gel	Not applicable	Not stated	EPAD electrodes meet functional test requirements per AAMI/ANSI EC12:2000: Disposable ECG Electrodes
Connectors	Nicomatic three pin	1.5 mm "TouchProof" - support any standard lead wires	Not stated	EPAD electrodes meet functional test requirements per AAMI/ANSI EC12:2000: Disposable ECG Electrodes
Current density	< 0.75 mA_{rms}/cm^2	Not applicable	Not stated	EPAD electrodes meet functional test requirements per AAMI/ANSI EC12:2000: Disposable ECG Electrodes
Sterility	Non-sterile, single patient use, disposable	Not applicable	Non-sterile, single patient use, disposable	No difference

*Per Protektor User and Service Manual.

**Per NeuroEPG 510(k) Summary for K123843.

4.9 Discussion of Differences

The key differences between the EPAD and the predicate devices are as follows:

- The EPAD is used for a limited subset of testing (SSEP NMJ) as compared to the predicate devices that perform these types of tests in addition to others (e.g., auditory and visual evoked potentials). This is the main reason driving the technical differences. However, all of the technical characteristics for EPAD are within those previously cleared for these types of devices.
- The EPAD System includes an algorithm to detect changes in evoked potential latency and amplitude as compared to baseline and alert the user to check the waveforms for artifact or possible position deficit. This feature is not offered on the predicate devices. However, this does not raise new questions of safety and effectiveness because it is an optional adjunct to standard waveform viewing.
- The EPAD System includes custom electrodes while the Protektor is labeled for use with off-the-shelf cutaneous electrodes. However, other evoked potential devices have been cleared with custom electrodes, including the named NeuroEPG. The EPAD electrode design is based on well-established principles for cutaneous electrodes and the electrodes meet the requirements of the ANSI/AAMI EC12:2000 standard (Section 5.2.2, Tests for Functionality).

4.10 Nonclinical Testing

The following nonclinical testing was conducted to demonstrate the safety and effectiveness of the EPAD System and support substantial equivalence to the predicate devices.

Software verification and validation testing was conducted in accordance with FDA's Guidance on the Content of Premarket Submissions for Software Contained in Medical Devices. The results of this testing demonstrated that all software requirements have been fulfilled and all software hazards have been mitigated. There are no unresolved anomalies in the EPAD software.

Biocompatibility testing on the patient contacting materials of the EPAD electrodes to the requirements of ISO 10993-1: Biological evaluation of medical devices-Part 1, Evaluation and Testing, demonstrated that the electrodes are safe for short term (<24 hours) contact with intact skin. Specific testing included cytotoxicity, sensitization, and irritation/intracutaneous reactivity.

Accelerated aging testing was conducted on the EPAD electrodes to establish a 15 month shelf life. All tests conducted following the accelerated aging of the electrodes in their final packaging were passed. The testing included the following:

- Impedance monitoring
- Visual inspection
- Testing in accordance with section 5.2.2 of ANSI/AAMI EC12:2000 for Disposable ECG Electrodes:
  - 10-Hz AC impedance, individual pair
  - Combined offset instability and internal noise
  - DC voltage offset, Bias test
- Electrode Impedance values on forearm
- Electrode evoked potential responses

Electrical Safety and electromagnetic compatibility testing was conducted to the following standards. All tests passed with no need for device modifications:

- UL60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, 1st ed with revisions through April 2006
- IEC 60601-1-1: Medical Electrical Equipment - Part 1-1: General Requirements for Safety-Collateral Standard: Safety Requirements for Medical Electrical Systems, 2nd ed, 2000
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety-; Electromagnetic Compatibility - Requirements and Tests, 3rd ed, 2007
- IEC 60601-2-40: Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment, 1st ed, 1998

FCC Certification Testing was conducted by the manufacturer of the EPAD Tablet to certify the Bluetooth wireless technology component to the FCC regulations under 47 CFR Part 15. All tests passed.

Functional Performance Testing was conducted by the EPAD system contract manufacturer to validate system performance requirements. All test results met the test protocol acceptance criteria

- EPAD Signal Quality Tests – These tests were conducted to validate the quality of the waveform signals from the Headbox to the Tablet
  - Noise level peak to peak on each channel
  - CMRR adjustment on each channel
  - Low Frequency Filter on each channel
  - High Frequency Filter on each channel
  - DC offset on each channel
  - Cross talk between each channel
  - Gain on each channel
  - Qualification of impedance circuit on each lead of each channel
- Wireless Coexistence Testing – To evaluate the EPAD Bluetooth communication performance in the presence of multiple wireless devices all transmitting simultaneously. There was no observed decline in data transmission between the EPAD Headbox and Tablet under the test conditions.
- Alert Algorithm Testing – The functionality of the EPAD algorithm designed to alert the clinician to check the evoked potential waveforms for evidence of possible position deficit was tested under minimal, moderate, and extreme noise conditions. The EPAD was able to detect waveform changes of reduced amplitude (>50%) and increased latency (>10%) under all noise conditions.

4.11 Conclusions Regarding Substantial Equivalence

The information and testing presented in this 510(k) demonstrate that the EPAD Evoked Potential Assessing Device is safe and effective for its intended use and substantially equivalent to the named predicate devices. The EPAD has the same intended use and substantially equivalent

indications for use. The main difference between the EPAD and the predicate devices is that the EPAD was designed specifically for peripheral nerve response (somatosensory evoked potential (SSEP)) and neuromuscular junction (NMJ) monitoring, while the predicate devices offer a broader range of monitoring modes, including auditory evoked responses. However, the technical specifications for electrical stimulation and waveform acquisition using the EPAD are within those of the predicate devices based on the publicly available information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 24, 2014

Safeop Surgical, Inc.
c/o Ms. Sheila Hemeon-Heyer
125 Cherry Lane
Amherst, MA 01002

Re: K132616
Trade/Device Name: EPAD
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF, IKN, GXY
Dated: December 23, 2013
Received: December 27, 2013

Dear Ms. Hemeon-Heyer:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act): 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132616

Device Name
EPAD

Indications for Use *(Describe)*
The EPAD is intended for use in monitoring neurological status by recording somatosensory evoked potentials (SSEP) or assessing the neuromuscular junction (NMJ).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S
2014.01.24 17:44:37 -05'00'

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."