May 22, 2021

Neurosoft Ltd
℅ Barry Ashar
Official Correspondent
Makromed, Inc.
88 Stiles Road
Salem, NH 03079 USA

Re: K190703
Trade/Device Name: Neuro-IOM system with Neuro-IOM.NET software, models - 32/B - 32/S - 16/S
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, GWE, GWJ, OLT, PDQ
Dated: April 9, 2021
Received: April 20, 2021

Dear Barry Ashar:

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,

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)*
K190703

Device Name
Neuro-IOM system with Neuro-IOM.NET software, models - 32/B - 32/S - 16/S

Indications for Use *(Describe)*
Neuro-IOM system with Neuro-IOM.NET software is a medical device intended for intraoperative neurophysiologic monitoring: the device provides information to assess a patient's neurophysiological status.

The system allows to monitor the functional integrity and/or mapping of central and peripheral nervous system including motor and sensory pathways.

It is provided in III different configurations:
I. 32/B
II. 32/S
III. 16/S
The system ensures the following IOM modalities: free-run EMG (electromyography), direct nerve stimulation including pedicle screw test, SSEP (somatosensory evoked potentials), MEP (motor evoked potentials), EEG (electroencephalography), AEP (auditory evoked potentials), VEP (visual evoked potentials), direct cortical stimulation. Also the train-of-four (TOF) stimulation is performed.

The system is not intended to measure the vital signs. It records the data to be interpreted by the neuromonitoring specialist.

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.

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510(k) Summary

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secondary contact:	Mr. Eugene Polezhaev
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Email:	polezhaev@neurosoft.ru

Date Summary Prepared: April 9, 2021

DEVICE IDENTIFICATION

Trade name:	Neuro-IOM system with Neuro-IOM.NET software, models - 32/B - 32/S - 16/S
Generic/ Common Name:	intraoperative neurophysiologic system
Regulation number:	21 CFR § 882.1870 Class II
Regulation name:	Evoked response electrical stimulator
Product Code:	GWF
Subsequent Product Codes:	GWE, GWJ, OLT, PDQ
Panel:	Neurology

PREDICATE DEVICES:

Neurosoft identified the following legally marketed devices as substantially equivalent:
- Xltek Protektor 32, NATUS MEDICAL, INC., K093304

DEVICE DESCRIPTION:
Neuro-IOM system with Neuro-IOM.NET software is a medical device intended for intraoperative neurophysiologic monitoring: the device provides information to assess a patient's neurophysiological status.

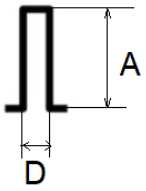
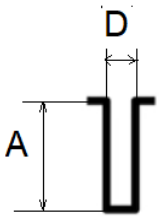
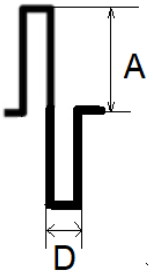
The system allows to monitor the functional integrity and/or mapping of central and peripheral nervous system including motor and sensory pathways.
It is provided in III different configurations:
I. 32/B
II. 32/S
III. 16/S

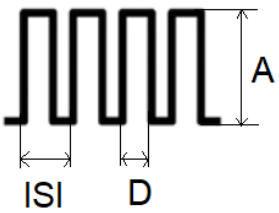
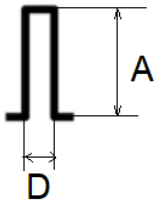
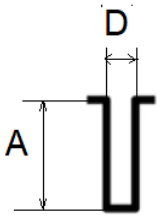
The system ensures the following IOM modalities: free-run EMG (electromyography), direct nerve stimulation including pedicle screw test, SSEP (somatosensory evoked potentials), MEP (motor evoked potentials), EEG (electroencephalography), AEP (auditory evoked potentials), VEP (visual evoked potentials, direct cortical stimulation. Also, the train-of-four (TOF) stimulation is performed.

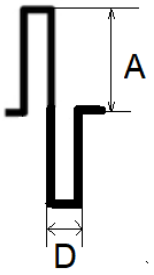
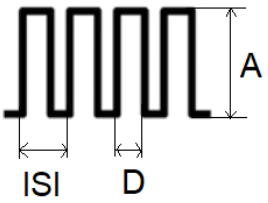
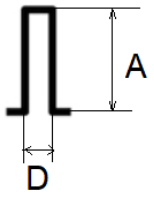
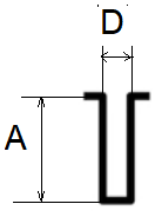
The system is not intended to measure the vital signs. It records the data to be interpreted by the neuromonitoring specialist.

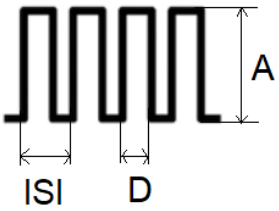
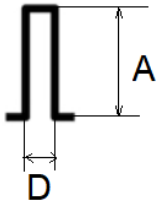
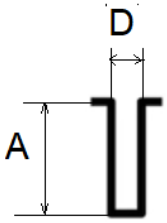
The systems can be used in operating rooms, intensive care units of different health care facilities (including clinics, hospitals, health centers, ambulance centers, etc.), specialized medical facilities (including prevention centers, medicine centers for emergency, military and medical expertise centers), research and educational medical and biological facilities where the neuromonitoring is required, only by qualified operators who have received training on these devices.

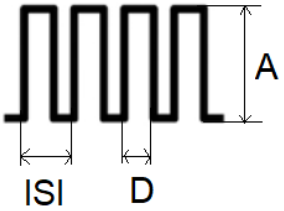
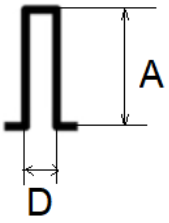
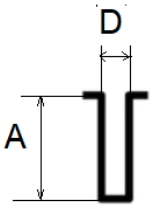
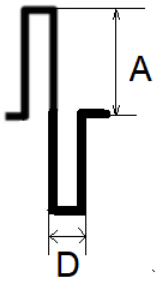
Description of stimuli

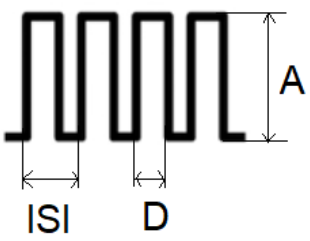
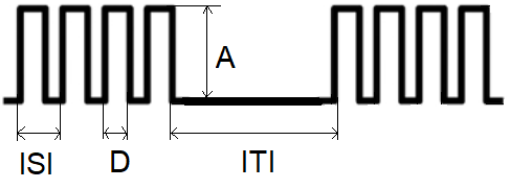
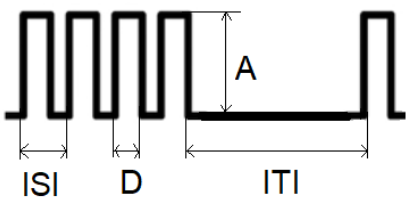
Stimulator	Picture	Modalities
Electrical Stimulator Built-in Electronic Unit	Single pulse monophasic normal  A – amplitude (0 – 200 mA, 0 – 400 V) D – duration (50 – 5000 µs)	SSEP, TOF
	Single pulse monophasic inverse  A – amplitude (0 – 200 mA, 0 – 400 V) D – duration (50 – 5000 µs)	SSEP, TOF
	Single pulse biphasic 	SSEP, TOF

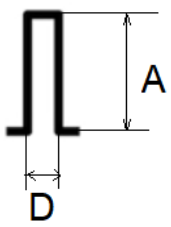
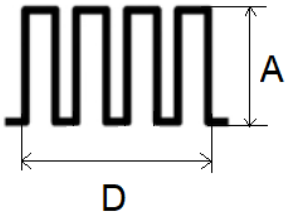
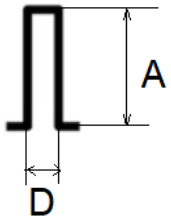
	A – amplitude (0 – 200 mA, 0 – 400 V) D – duration (50 – 5000 µs)	
	Train of pulses  A – amplitude (0 – 200 mA, 0 – 400 V) D – duration (50 – 5000 µs) ISI – interstimulus interval (3 – 10 ms) N – number of pulses (2 - 200)	MEP
Low Current Stimulator Built-in Electronic Unit	Single pulse monophasic normal  A – amplitude (0 – 20 mA, 0 – 30 V) D – duration (50 – 500 µs)	Direct nerve stimulation
	Single pulse monophasic inverse  A – amplitude (0 – 20 mA, 0 – 30 V) D – duration (50 – 500 µs)	Direct nerve stimulation
	Single pulse biphasic	Direct nerve stimulation

	 A – amplitude (0 – 20 mA, 0 – 30 V) D – duration (50 – 500 µs)	
	Train of pulses  A – amplitude (0 – 20 mA, 0 – 30 V) D – duration (50 – 500 µs) ISI – interstimulus interval (2 - 10 ms) N – number of pulses (1 - 200)	Direct nerve stimulation
Electrical Stimulator Built-in Amplifier Unit	Single pulse normal  A – amplitude (0 – 200 mA) D – duration (50 – 5000 µs)	SSEP, TOF
	Single pulse inverse  A – amplitude (0 – 200 mA)	SSEP, TOF

	D - duration (50 – 5000 µs)	
	Train of pulses  A – amplitude (0 – 200 mA) D – duration (50 – 5000 µs) ISI – interstimulus interval (2 - 10 ms) N – number of pulses (1 - 255)	MEP
Low Current Stimulator Built-in Amplifier Unit	Single pulse normal  A – amplitude (0 – 20 mA) D – duration (50 – 500 µs)	Direct nerve stimulation
	Single pulse inverse  A – amplitude (0 – 20 mA) D – duration (50 – 500 µs)	Direct nerve stimulation
	Train of pulses	Direct nerve stimulation

	 A – amplitude (0 – 20 mA) D – duration (50 – 500 µs) ISI – interstimulus interval (2 – 10 ms) N – number of pulses (1 - 255)	
Transcranial Electrical Stimulator	Single pulse monophasic normal  A – amplitude (1 – 1000 V) D – duration (40 – 200 µs)	MEP
	Single pulse monophasic inverse  A – amplitude (1 – 1000 V) D – duration (40 – 200 µs)	MEP
	Single pulse biphasic 	MEP

	A – amplitude (1 – 1000 V) D – duration (40 – 200 µs)	
	Train of pulses  A – amplitude (1 – 1000 V) D – duration (40 – 200 µs) ISI – interstimulus interval (1 – 10 ms) N – number of pulses (1 – 9)	MEP
	Double train  A – amplitude (1 – 1000 V) D – duration (40 – 200 µs) ISI – interstimulus interval (1 – 10 ms) ITI – intertrain interval (10 – 100 ms)	MEP
	Train + Pulse  A – amplitude (1 – 1000 V) D – duration (40 – 200 µs) ISI – interstimulus interval (1 – 10 ms)	MEP

	ITI – interval between train and pulse (10 – 100 ms)	
Auditory Stimulator	Click  A – amplitude (0 – 120 dB) D – duration (100 – 5000 µs)	AEP
	Tone  A – amplitude (0 – 120 dB) D – duration (0.1 – 90 ms) Tone frequency – 100 – 5000 Hz	AEP
Visual Stimulator	 D – duration (2 - 1500 ms) Max. luminance - 1500 cd/m^2	VEP

INDICATIONS FOR USE:
Neuro-IOM system with Neuro-IOM.NET software is a medical device intended for intraoperative neurophysiologic monitoring: the device provides information to assess a patient's neurophysiological status.

The system allows to monitor the functional integrity and/or mapping of central and peripheral nervous system including motor and sensory pathways.

It is provided in III different configurations:
I. 32/B
II. 32/S
III. 16/S

The system ensures the following IOM modalities: free-run EMG (electromyography), direct nerve stimulation including pedicle screw test, SSEP (somatosensory evoked potentials), MEP (motor evoked potentials), EEG (electroencephalography), AEP (auditory evoked potentials), VEP (visual evoked potentials), direct cortical stimulation. Also, the train-of-four (TOF) stimulation is performed.

The system is not intended to measure the vital signs. It records the data to be interpreted by the neuromonitoring specialist.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL E Q U I V A L E N C E:

In support of a substantial equivalence determination, hereunder are comparison charts with the submitted device and the predicate devices.

Hardware Comparison – Chart 1

ATTRIBUTE / CHARACTERISTICS	Neuro-IOM 16S, 32S, 32B Neurosoft Ltd (Submitted Product)	Xltek Protektor 32 NATUS MEDICAL, INC	Why the differences do not adversely affect the safety and effectiveness
"K" numbers	NA	K093304	
Proprietary / Trade Name	Neurosoft Ltd/Neuro-IOM 16S, 32S, 32B with Neuro-IOM.NET software	Xltek Protector 32	
CFR Section	882.1870	882.1870	Same
Pro-code	GWF, GWE, GWJ, OLT	GWF, GWE, GWJ, OLT	Same
Classification name	Stimulator, Electrical, Evoked Response	Stimulator, Electrical, Evoked Response	Same
Intended Use	Neuro-IOM system with Neuro-IOM.NET software is a medical device intended for intraoperative neurophysiologic monitoring: the device provides information to assess a patient's neurophysiological status. The system allows to monitor the functional integrity and/or mapping of central and peripheral nervous system including motor and sensory. It is provided in III different configurations: I. 32/B II. 32/S III. 16/S The system ensures the following IOM modalities: free-run EMG (electromyography), direct nerve stimulation including pedicle screw test, SSEP (somatosensory evoked potentials), MEP (motor evoked potentials), EEG (electroencephalography), AEP (auditory evoked potentials), VEP (visual evoked potentials), direct cortical stimulation. Also, the train-of-four (TOF) stimulation is performed. The system is not intended to measure the vital signs. It records the data to be interpreted by the neuromonitoring specialist.	The Protektor32 channel system, composed of both hardware and software, is intended to be used for intraoperative neurological monitoring. The instrument uses Electroencephalography (EEG), Evoked Potentials (EP), Electromyography (EMG) and Transcranial Motor Evoked Potential (TcMEP) stimulation techniques to provide the healthcare professionals with information to help assess a patient's neurological status during surgery. The TcMEP mode is intended for intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency. The EPWorks software, an integral part of the system, is intended to allow a medical professional to manually configure stimulation and acquisition parameters and to manually create EEG, EP, EMG and TcMEP protocols according to their own requirements. The intended use, for each of the software's output, is as follows: • The EEG, EP, and EMG waveforms are	

		intended to help the user assess a patient's neurological status during surgery. • Simple waveform parameters (e.g., amplitude. latency), and user-defined Fast Fourier transform (FFT) displays (compressed spectral array or CSA, density spectral array or OSA) are intended to help the user analyse the EEG and EP waveforms. This device is intended to be used by qualified medical practitioners, trained in EEG, EP and EMG who will exercise professional judgment when using the information.	
Intended User	The device is to be used by trained personnel only	The device is to be used by trained personnel only	Same
Device Hardware Setup	Connected to PC, not standalone	Connected to PC, not standalone	Same
Standards	AAMI/ANSI ES 60601-1:2005/(R)2012 IEC 60601-1-2:2014 IEC 60601-1-6:2013 IEC 60601-2-40:2016 IEC 62366-1:2015 AAMI/ANSI 62304:2006 ISO series 10993 IEC 60068-2-31:2008 IEC 60068-2-80:2005 ISO 14971:2007 ISO 13485:2012	IEC 60601-1:2000 IEC 60601-1-1:2000 IEC 60601-1-2:2005 IEC 60601-2-40:1998 IEC 61000-4-2:2001 IEC 61000-4-3:2002 IEC 61000-4-4:2004 IEC 61000-4-5:2005 IEC 61000-4-6:2006 IEC 61000-4-8:2001 IEC 61000-4-11:2004 61000-3-3:2002 ISO 15223:2000	
Workflow, Menu	PC-controlled	PC-controlled	Same
Interface to Computer	USB	USB	Same
Amplifiers			
Channels	16/32	16/32	Same
1.5 mm touch-proof input jacks on pods	Same	Same	Same
Cable Length	5 m	10 ft., 20 ft.	
Input impedance	>1000 MOhm	>100 MOhm	Since the higher input impedance in our device improves the quality of signal

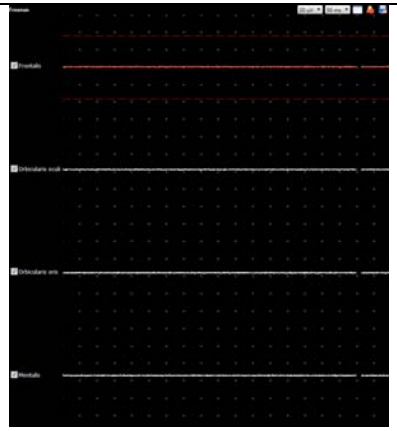
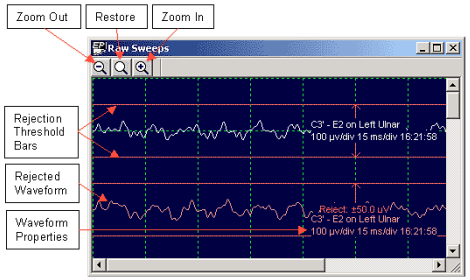
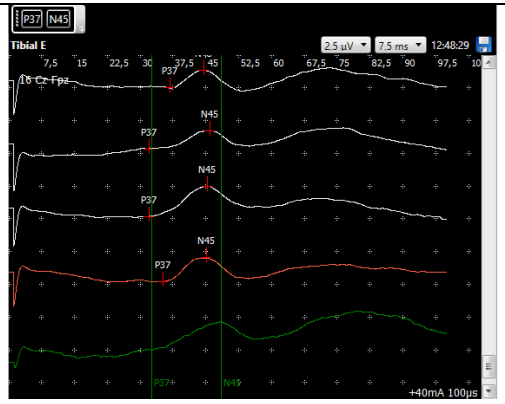
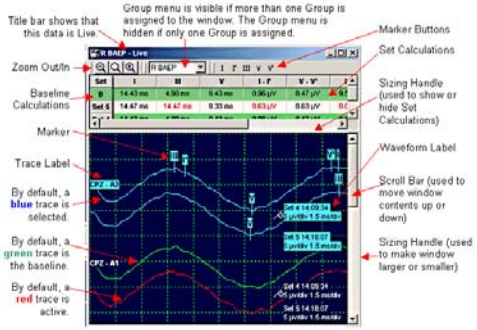
			registration, there is no adverse impact on the safety and effectiveness.
Common Mode Rejection (CMRR)	>90 dB	>93 dB	The difference is negligible to impact safety and effectiveness.
Low Frequency Filters	0.2 Hz -2000 Hz	0.1 - 500 Hz	Higher cutoff frequency in our device means that it will effectively cut off low-frequency oscillations cut off by the predicate device.
High Frequency Filters	10 Hz - 4 KHz	30Hz - 15KHz	The range covered by our device is sufficient for recording signals properly and will effectively eliminate the high-frequency interference encountered in operating rooms. The difference is negligible to impact the safety and effectiveness.
Notch Filter	50/60 Hz	50/60 Hz	same
Sample Rate	50 KHz	60 KHz	The difference is negligible to impact safety and effectiveness.
Sensitivity	0.05 µV/division to 20 mV/division	0.1 µV/division to 5 mV/division	Wider range of our device is favorable as it would allow displaying lower- and higher-amplitude signals.
Noise Level	< 0,6 µV (< 9,5 nV/√Hz)	< 0.1 µV (< 20nV/√Hz)	Our device has a lower noise level parameter compared to the declared value of the parameter in the technical manual of the predicate.
Artifact Rejection	Independent for each channel	Independent for each channel	Same
Stimulators			
Electrical			
Number of channels	16/12/4/4	16	
Max Intensity	200 mA	100 mA	Larger amplitude of the stimulus allows use of the stimulator for transcranial stimulation. No impact on the safety or effectiveness.
Duration	0.02 - 5 ms	0.05 - 1 ms	The difference is negligible to impact

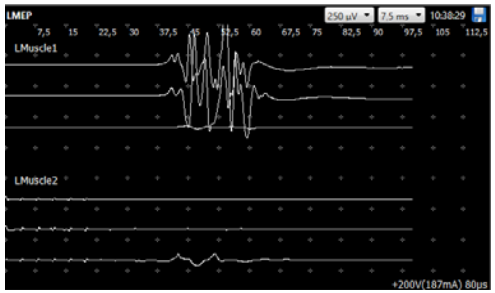
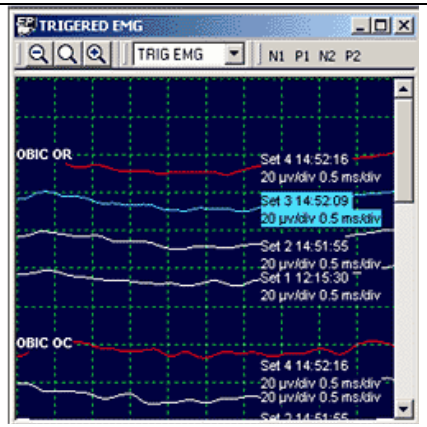
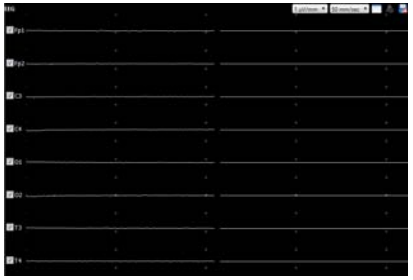
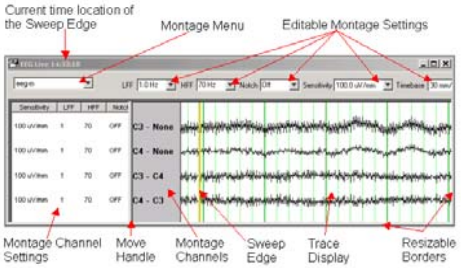
			safety and effectiveness.
Stimulus Type	Mono-/biphasic	Mono-/biphasic	Same
Electrical Modes	Single, repetitive, trains	Single, repetitive, trains	Same
Transcranial Electrical stimulator **Number of Channels** **Max Intensity** **Duration**	 4 1000 V 0.04 - 0.2 ms	 4 1000 V 0,05 ms	Increasing the duration of the stimulus allows obtaining a response at lower amplitude of the stimulus. No effect on safety or effectiveness.
Low current stimulator **Number of Channels Max Intensity Duration**	 3/2/1 20 mA 0.05 – 0.5 ms	 2 20 mA 0.05 - 1 ms	Similar
Auditory			
Stimulation Type	Click, tone, noise	Click, pip, tone, noise	Similar
Rate	0.01 - 100 Hz	0.2 - 100 Hz	Similar
Intensity	120 dB nHL	125 dB nHL	For patient comfort, lower value is better.
Polarity	Condensation, rarefaction, alternating	Condensation, rarefaction, alternating	Same
Transducers	Insert earphone EAR-3A-10 Ohms	TDH - 39 headphones, TIP inserts	Similar
Visual			
Rate	0.01 – 100 Hz	0.1 - 100 Hz	Same
Color	red	Black, red, green, blue	Similar
Recording modalities			
SSEP	Yes	Yes	Same
MEP	Yes	Yes	Same
TcMEP	Yes	Yes	Same
BAEP	Yes	Yes	Same
VEP	Yes	Yes	Same
EMG	Yes	Yes	Same
EEG	Yes	Yes	Same
Multimodality	Yes	Yes	Same
Software features			
Predefined test templates	Yes	Yes	Same
Creation and editing of test templates	Yes	Yes	Same

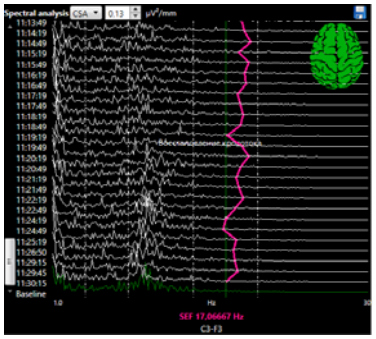
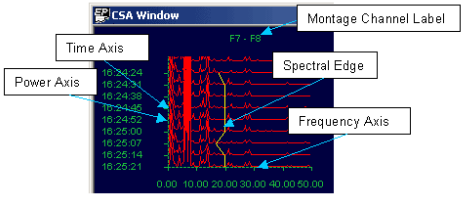
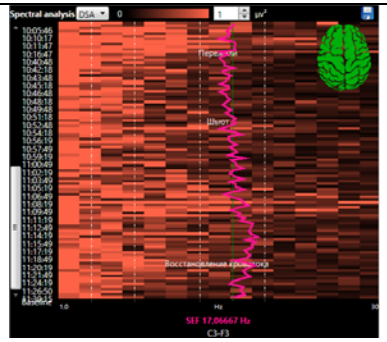
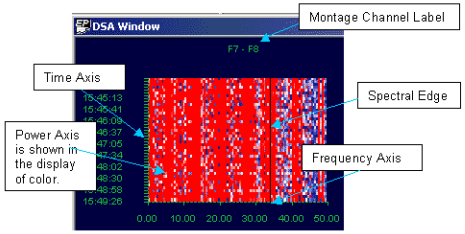
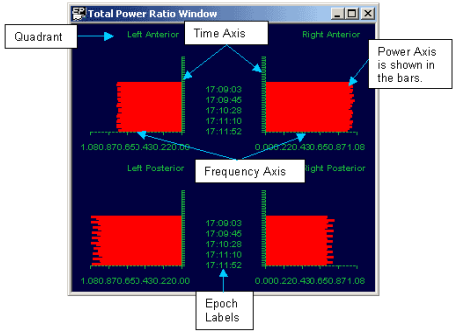
Generation of neuromonitoring report	Yes	Yes	Same
Image review from microscope or other sources	Yes	Yes	Same
Trending	Yes	Yes	Same
ESU Detection	Yes	Yes	Same
Power supply	220/230 V AC 50/60 Hz	100 - 240 V AC 50/60 Hz	Similar
Accessories			
Visual	LED goggles	LED goggles	Same
Type of electrodes	Any legally marketed (in the U.S.) probes and surface or needle electrodes with standard lead wire.	Any legally marketed (in the U.S.) probes and surface or needle electrodes with standard lead wire.	Equivalent – no significant difference in charge density or current density expected.

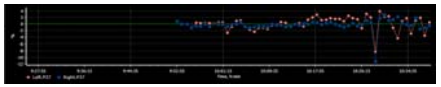
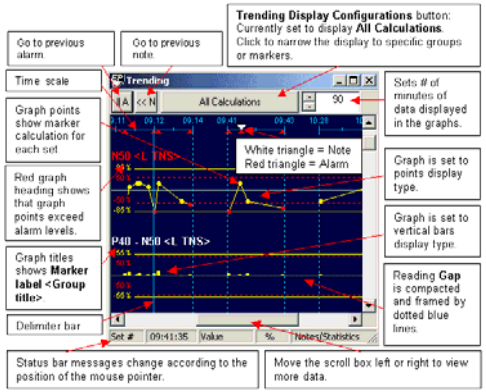
Software Comparison – Chart 2

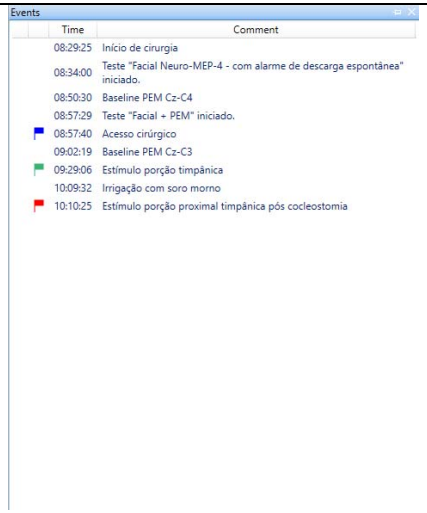
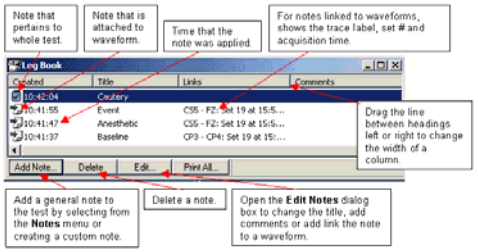
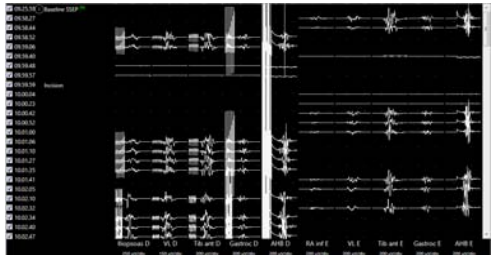
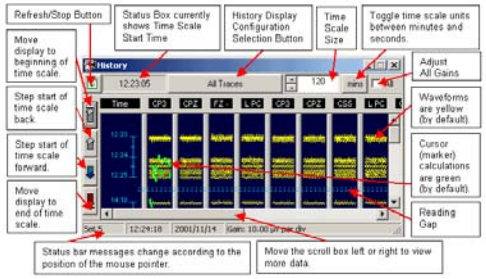
ATTRIBUTE / CHARACTERISTICS	NEURO-IOM.NET SOFTWARE NEUROSOFT (Submitted Product)	XItek Protektor 32 Natus	Why the differences do not adversely affect the safety and effectiveness
'K" numbers		K093304	
Indications For Use	Neuro-IOM system with Neuro-IOM.NET software is a medical device intended for intraoperative neurophysiologic monitoring: the device provides information to assess a patient's neurophysiological status. The system allows to monitor the functional integrity and/or mapping of central and peripheral nervous system including motor and sensory pathways. It is provided in III different configurations: I. 32/B II. 32/S III. 16/S The system ensures the following IOM modalities: free-run EMG (electromyography), direct nerve stimulation including pedicle screw test, SSEP (somatosensory evoked potentials), MEP (motor evoked potentials), EEG (electroencephalography), AEP (auditory evoked potentials), VEP (visual evoked potentials), direct cortical stimulation. Also, the train-of-four (TOF) stimulation is performed. The system is not intended to measure the vital signs. It records the data to be interpreted by the neuromonitoring specialist.	The EPWorks software, an integral part of the system, is intended to allow a medical professional to manually configure stimulation and acquisition parameters and to manually create EEG, EP, EMG and TcMEP protocols according to their own requirements. The intended use for each of the software's outputs is as follows: 1.The EEG, EP, and EMG waveforms are intended to help the user assess a patient's neurological status during surgery. 2.Simple waveform parameters (e.g., amplitude. latency), and user-defined Fast Fourier transform (FFT) displays (compressed spectral array or CSA, density spectral array or OSA) are intended to help the user analyze the EEG and EP waveforms.	
Functions			

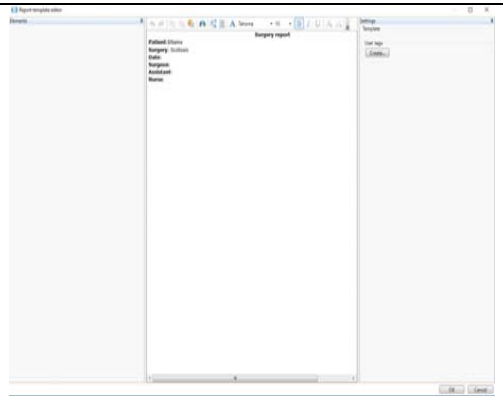
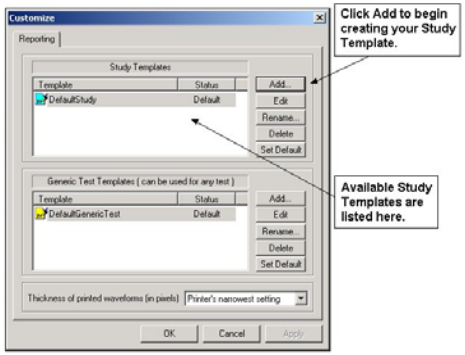
ATTRIBUTE / CHARACTERISTICS	NEURO-IOM.NET SOFTWARE NEUROSOFT (Submitted Product)	XItek Protektor 32 Natus	Why the differences do not adversely affect the safety and effectiveness
1-Freerun waveform			Equivalent – users can change scale and threshold.
2- SSEP, AEP, VER (averaged) waveform			Equivalent – users can change scale. Automatic markers setup and manual correction are available.

ATTRIBUTE / CHARACTERISTICS	NEURO-IOM.NET SOFTWARE NEUROSOFT (Submitted Product)	Xltek Protektor 32 Natus	Why the differences do not adversely affect the safety and effectiveness
3- MEP (triggered) waveform			Equivalent – users can change scale. Automatic markers setup and manual correction are available.
4- EEG window			Equivalent – users can change scale.

ATTRIBUTE / CHARACTERISTICS	NEURO-IOM.NET SOFTWARE NEUROSOFT (Submitted Product)	Xltek Protektor 32 Natus	Why the differences do not adversely affect the safety and effectiveness
5-CSA window			Equivalent – users can see spectrums and spectrum edge traces.
6- DSA window			Equivalent – users can see density spectrum array and spectrum edge trace.
7-Total power window	NO		This function presented only in Xltek Protektor software and is not fundamental to perform the analysis of EEG for diagnostic purposes.

ATTRIBUTE / CHARACTERISTICS	NEURO-IOM.NET SOFTWARE NEUROSOFT (Submitted Product)	XItek Protektor 32 Natus	Why the differences do not adversely affect the safety and effectiveness
		The **Total Power Ratio window** shows the ratio of high frequency to low frequency activity in each quadrant. **Delta**, **Theta**, **Alpha**, **Beta** bands are defined in the **Spectral Settings** dialog box..	
8-Trending window			Equivalent – user can see param trend plots and change colors and time scale. .

ATTRIBUTE / CHARACTERISTICS	NEURO-IOM.NET SOFTWARE NEUROSOFT (Submitted Product)	Xltek Protektor 32 Natus	Why the differences do not adversely affect the safety and effectiveness
9 -Log book window			Equivalent – users can see notes and time associated, and change note title.
10-History window			Equivalent – user can change scale and traces number.

ATTRIBUTE / CHARACTERISTICS	NEURO-IOM.NET SOFTWARE NEUROSOFT (Submitted Product)	Xltek Protektor 32 Natus	Why the differences do not adversely affect the safety and effectiveness
11-Report templates			Equivalent – user can create report template, including report header.
12 - Remote monitoring	YES. User can use internet browser for observing acquisition computer screen.	YES. User need to use special software to access and view monitoring data remotely.	Equivalent – user can see acquisition station screen and use chat window for conversation.

SUBSTANTIAL EQUIVALENCE DISCUSSION:

Based on the analysis of its hardware specifications the subject device Neuro-IOM system manufactured by Neurosoft Ltd is substantially equivalent to the predicate device Xltek Protektor manufactured by Natus Inc.

Both the devices are intended for intraoperative neurophysiologic monitoring, to assess a patient's neurological status during surgery. The subject device incorporates the same fundamental scientific technology and has functional characteristics which are the same or equivalent to those of the predicate device. They have the same principle of operation, main specifications and safety. Stimulation type is the same, the duration and frequency range is quite similar. They have the same recording modalities and software features.

As for the software, the processing functions for both the subject device and predicate devices are well known and accepted as the conventional tools.
The Neuro-IOM.NET software resides on a PC like Xltek Protektor 32 and it has indications for use and characteristics that are a subset of the ones of Xltek Protektor 32. The functions of the Neuro-IOM.NET software are a sub-group of the ones of the software of the predicate device. These functions are generic for both devices.
The predicate devices substantially perform the same operations and the minor differences consist in graphical appearance of the control icons and graphical appearance on displaying the results. These minor differences do not raise any new hazard, they don't increase the risk of inappropriate signal capture or the risk of an erroneous interpretation of the results by the operator or the risk of an erroneous processing, thus no additional safety and effectiveness issues arise.

DISCUSSION OF NONCLINICAL TESTS
Nonclinical tests were conducted to demonstrate substantial equivalence to the predicate device.

The following performance data were provided in support of the substantial equivalence determination.

N	Standard/guidance used for testing	Test method	Summary of the results
Biocompatibility testing			
1.	ISO 10993-1-2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	-	- the principles governing the biological assessment of medical devices in the risk management process were evaluated; - the medical device is classified according to the nature and duration of their contact with the body;
Cytotoxicity			
2.	ISO 10993-5 Medical devices. Biological evaluation of medical devices. Part 5. Tests for	The methods described in clause 8 of	The cytotoxicity of live cells was studied on suspense cultures with

	in vitro cytotoxicity	this ISO	the calculation of toxicity index
Irritation			
3.	ISO 10993-10 Medical devices. Biological evaluation of medical devices. Part 10. Test for irritation and delayed-type hypersensitivity	The methods described in clause 6 of this ISO	The systemic acute toxicological experiments were performed in rabbits.
Systemic toxicity			
4.	ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	The methods described in clause 5 of this ISO	The systemic acute toxicological experiments were performed in rabbits.
Electrical safety and electromagnetic compatibility (EMC)			
5.	AAMI/ANSI ES 60601-1:2005/(R2012) and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD);	Electrical safety testing was conducted on the Neuro-IOM device, in accordance with the requirements of the standard	The system complies with the AAMI/ANSI ES 60601-1
6.	IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.	EMC testing was conducted on the Neuro-IOM device, in accordance with the requirements of the standard	The system complies with the IEC 60601-1-2:2014
Performance tests			
7.	IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	The system usability check was carried out in accordance with the requirements of the standard	The system complies with the IEC 60601-1-6
8.	IEC 60601-2-40 Medical electrical equipment - Part 2-40:	The system check in accordance with the requirements of the	The system complies with the IEC 60601-2-40

	Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment	standard	
9.	IEC 60068-2-31 Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	System check for environmental tests	The system complies with the IEC 60068-2-31
10.	IEC 60068-2-80 Environmental testing - Part 2-80: Tests - Test Fi: Vibration - Mixed mode		The system complies with the IEC 60068-2-80
11.	IEC 80601-2-26:2019 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph	The system performance check based on standard requirements	The system complies with the IEC 80601-2-26:2019
Software Verification and Validation Testing			
12.	Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."	Software verification and validation testing were conducted and documentation was provided as recommended by FDA's	Safety Level of the Software Device is **Moderate**.

CONCLUSION:

Neurosoft believes that the submitted Neuro-IOM system with Neuro-IOM software is substantially equivalent in its intended use, technological specifications, principle of operation, and processing functions to the predicate device based on the supported nonclinical testing.