March 25, 2024

Soterix Medical, Inc.
Danielle Dadona
Regulatory Affairs Specialist
1480 U.S. Highway 9 North
Suite 204
Woodbridge, New Jersey 07095

Re: K234080
Trade/Device Name: MEGA-IOM system with Neuro-IOM.NET software (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: December 22, 2023
Received: December 22, 2023

Dear Danielle Dadona:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234080

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

Indications for Use *(Describe)*
MEGA-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 three 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 potential), MEP (motor evoked potential), EEG (electroencephalography), AEP (auditory evoked potential), VEP (visual evoked potentials), direct cortical stimulation. Also the train-of-four (TOF) stimulation is performed.

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

MEGA-IOM system is intended for use in adults age 18 years and older.

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."

K234080
Traditional 510(k) SUMMARY
MEGA-IOM System

Date Prepared:	February 29, 2024
Submitter Information	
Company and Manufacturer Name:	Soterix Medical, Inc. 1480 US Highway 9 North Suite 204 Woodbridge, NJ 07095
Contact Person:	Danielle Dadona Phone: 888-990-8327 Fax: 212-315-3232
Device Information	
Trade Name:	MEGA-IOM system with Neuro-IOM.NET software models -32/B -32/S -16/S
Common Name:	Intraoperative Neurophysiologic System
Classification and Product Code:	21 CFR 882.1870, Class II GWF - Evoked response electrical stimulator
Device Class:	Class II
Predicate Device:	**K190703** Neuro-IOM system with Neuro-IOM.NET software models -32/B -32/S -16/S Neurosoft Ltd 21 CFR 882.1870, GWF, Class II

Device Description	The MEGA-IOM system with Neuro-IOM.NET software is intended for intraoperative neurophysiological monitoring (IOM). The system is intended for monitoring the functional integrity and/ or mapping of central and peripheral nervous system including motor and sensory pathways. Soterix Medical is assuming manufacturing of the predicate product cleared in **K190703**. This 510(k) submission includes the same hardware cleared with the predicate device system (no changes) and an updated version of the software compared to the predicate device. Below, a high-level summary of the changes from the predicate are provided: **Software**: The primary changes in this 510(k) submission are related to the software. The changes are troubleshooting updates for greater usability such as user interfaces and bug fixes. Detailed descriptions of these software changes per version are provided below: **Version 1.1.52.7:** Fixes related to the stimulation stop after a few hours, adding a stimuli limit for double train stimulation, allowing pulse duration (200 μs) entry, masking noise limitation per IEC 60601-2-40 (Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment), reporting correct status of multichannel operation, prevent skipping of traces, and check for incompatible stimulation parameter entry. **Version 1.1.52.8:** Fixes related to facilitating quick turning off stimulation, real-time stimulus change control, scrolling in spectral setup window, constraining window within pattern printout to screen, ensuring modality window description is unchanged, incorrect Ch 17 display in emulation mode, video filters error during installation, ensuring all text is displayed within visibility area, incorrect auditory evoked potentials (EPs) average calculation in emulation mode. **Version 1.1.52.9:** Fixes related to exam saved message, flexibility to change test template sequence, sleep mode prevention, rendering speed, interpulse interval display correction, allowing comments in the event window, automatic creation of user template, template list update, impedance measurement window rendering, parameter display correction in EMG trigger window and Group mode, ensuring non-disappearance of red line around patient's birth date, enabling stimulation via local menu in

	Scoliosis test template, frame switching error during video recording, displaying correct device status. **Version 1.1.53.7:** Fixes related to addition of video clip creation button, accidental stimulation activation protection, display of preliminary train in double train mode, voltage and charge value display in stimulation panel, allowing repetitive stimulation in Double Train and Train+Pulse modes, option to view amplitude values up to 10 µA, option to select scales in X axis, option to delay auto saving if stimulation in progress, option to titrate stimulation amplitude using mouse wheel, option to select grid type, confirmation on layout uninstallation, addition of the Pause button in Stimulation programs, option to select motor response search interval and displaying the motor response search interval, addition of measured impedance visualization, offering first the windows already available when adding a new window, preventing closure of window if input row is active in derivation test, enable display of additional TOF parameters, option to playback trace fragments, addition of Take a screenshot command, parameter trend export, pulse duration interval display in TES train, option to enter multiple-line comments, option to re-name layout, option to hide command list, ability to save only responses beyond a certain level, stimulator list scrolling, RMS noise value display, test template cloning, motor response onset marker, previous recorded traces display, layouts during new test reset, stimulator reminder mod, video file duration based on frame rate, saving of the number of traces, test template rewriting, group trace visualization display, layout switching, stimulation resumption post coagulator off, video playback if another program is run. **Version 1.1.53.8:** Fixes related to allowing multiple image view within the image window, allowing EEG artifact recording, showing baseline in the Overlay mode, option to disable program, option to save screen shots to a specific folder, stimulation program panel addition, correction of auto-increment window bug, correction of DSA rendering. **Version 1.1.53.9:** Fixes related to custom scale adjustment in Freerun window, randomly changing pulse intervals in multichannel mode, event trace copy to report, layout panel updating post deletion, sound, threshold, and color parameter display during new site addition, EMG channels in template during long-term monitoring, site visibility during stimulation in presence of temporary markers, auto sweep resets, temporary markers display, trace export to EDF, layout non-save post video window opening, type conversion in trace window. **Version 1.53.10:** Fixes related to video window copying over to report,

	trace scale reset, appearance of average trace display in case of no averages due to artifacts, site name display in TOF window, saving of initial study state in autosave mode, incomplete installation of video components, volume increment of auditory stimulator signal volume. **Version 1.1.53.11:** Fixes related to active probe switch-off during monitoring, limiting maximum increment adjustment of electrical stimulation amplitude to 1 mA and 5V, stimulus duration set-up when stimulation amplitude is increased, stimulation disablement after power supply resume, stimulus sound notification, text visualization in dialogue box, non-active stimulator panel, maximum stimulus artifact width display, minimum and maximum MEP trace markers. **Version 1.1.53.12:** Fixes related to pulse width change during stimulation in multichannel mode, MS Office word report, TeamViewer, logo, and translation corrections. **Version 1.1.53.13:** Fixes related to removal of sites containing TOF and logo change. **Version 1.1.53.14:** Fixes related to start monitoring during video camera switch off, video recording in some interface languages, sound disablement during impedance measurement, printing test template, USB driver-related Windows 10 OS bugs. In summary, the aforementioned software changes are related to resolving software bugs and increasing user convenience, but the changes do not impact the intended use, indications for use statement, contraindications, or warnings. They also don't increase the likelihood that the device will be used by a broader or different group of users and do not raise any new risks. **Labeling**: Modifications have been made to labeling and these changes are related to the new device trade name and change in manufacturer. Instances of "Neuro-IOM" were changed to "MEGA-IOM" in the user manual and on the device labels. Soterix Medical is named the manufacturer and point of contact in the labeling including for all complaints and service requests. **Waveforms**: The MEGA-IOM system has the same waveforms as the predicate device. No change to the waveforms.
Intended Use:	MEGA-IOM system with Neuro-IOM.NET software is intended for intraoperative neurophysiologic monitoring. The device provides information to assess a patient's neurophysiological status by evoking a

	response to electrical stimulation by means of skin electrodes. The system allows to monitor the functional integrity and/or mapping of central and peripheral nervous system including motor and sensory pathways. The system is not intended to measure vital signs. It records the data to be interpreted by the neuromonitoring specialist.
Technological Comparison	The MEGA-IOM uses the same technological principle as the predicate device to accomplish the same intended use, namely intraoperative neurophysiological monitoring. All device components, accessories, and output specifications are the same as the predicate device.

Basis for Equivalence	
Performance Testing	To account for the proposed software changes in this 510(k) submission, non-clinical performance testing was submitted in the form of software verification and validation and related risk management updates demonstrate that the performance parameters of the MEGA-IOM device are substantially equivalent to that of the predicate device. The software verification and validation testing documentation in accordance with a Moderate level of concern device was provided as recommended by the FDA's Guidance for Industry and FDA Staff "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*."

Table: Comparison of Technological Characteristics

Parameter	MEGA-IOM Subject Device	Neuro-IOM Predicate Device	Comment
510(k)	K234080	K190703	--
Device Name and Model	MEGA-IOM 16S, 32S, 32B with Neuro-IOM.NET software	Neuro-IOM 16S, 32S, 32B with Neuro-IOM.NET software	--
Manufacturer	Soterix Medical Inc.	Neurosoft Ltd	--

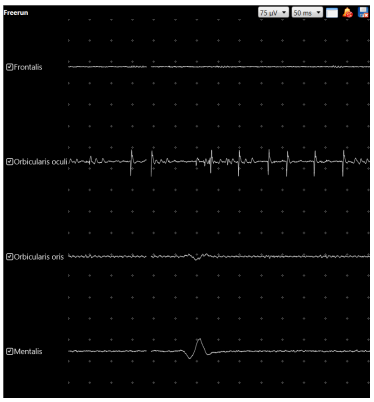
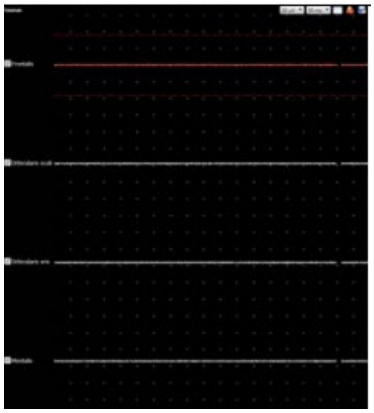
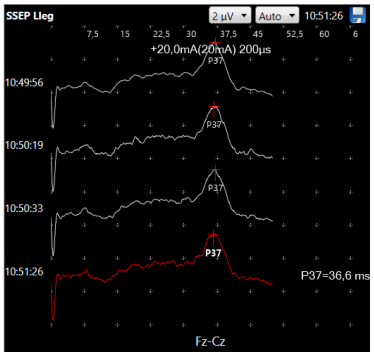
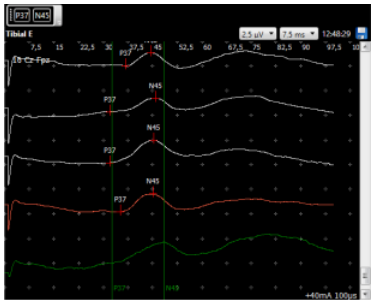
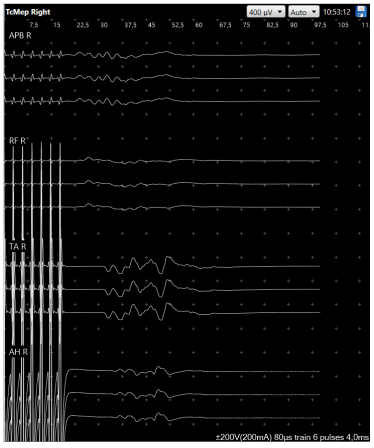
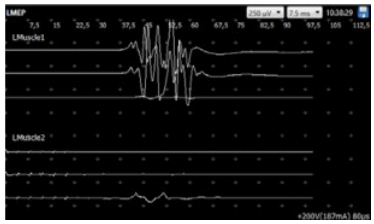
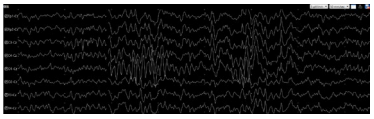
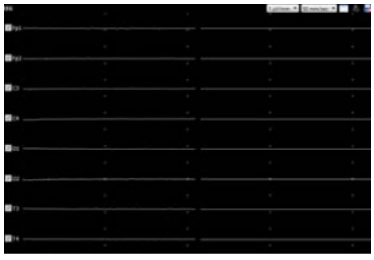
Parameter	MEGA-IOM Subject Device	Neuro-IOM Predicate Device	Comment
Classification Name	Stimulator, Electrical, Evoked Response	Stimulator, Electrical, Evoked Response	**Identical**
Product Codes	GWF (primary), GWE, GWJ, OLT, PDQ	GWF (primary), GWE, GWJ, OLT, PDQ	**Identical**
Regulatory Class	Class II	Class II	**Identical**
Classification Number	21 CFR 882.1870	21 CFR 882.1870	**Identical**
Indications for Use (IFU) statement	MEGA-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 three 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 potential), MEP (motor evoked potential), EEG (electroencephalography), AEP (auditory evoked potential), VEP (visual evoked potentials), direct cortical	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	**Similar; The new IFU includes the new device name. All other wording is identical to the predicate IFU statement**

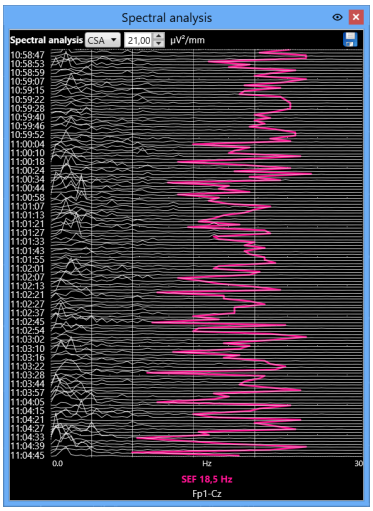
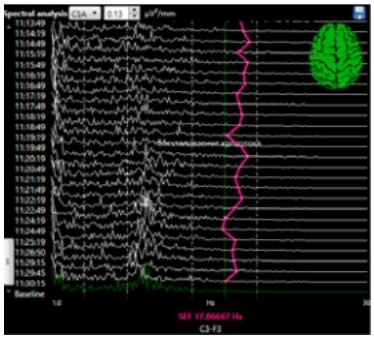
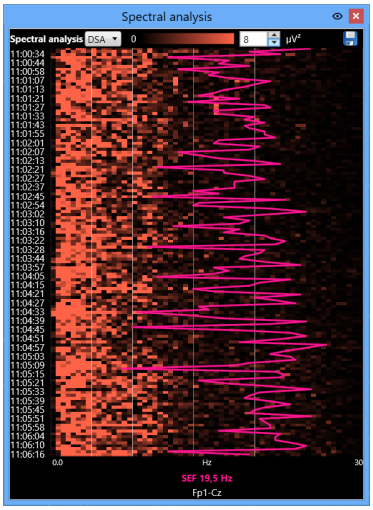
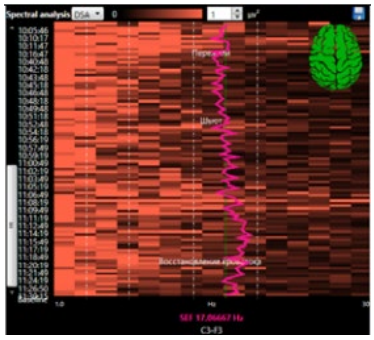
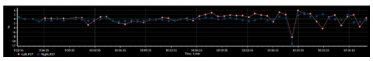
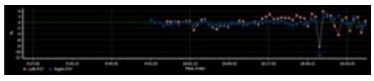
Parameter	MEGA-IOM Subject Device	Neuro-IOM Predicate Device	Comment
	stimulation. Also the train-of-four (TOF) stimulation is performed. The system is not intended to measure vital signs. It records the data to be interpreted by the neuromonitoring specialist. MEGA-IOM system is intended for use in adults age 18 years and older.	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.	
Intended User	The device is to be used by trained personnel only.	The device is to be used by trained personnel only.	**Identical**
Device Hardware Setup	Connected to PC, not standalone.	Connected to PC, not standalone.	**Identical**
Electrical Safety 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 14971:2019 ISO 13485:2016	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	Subject device conforms to updated versions of standards.
Workflow, Menu	PC-controlled	PC-controlled	**Identical**

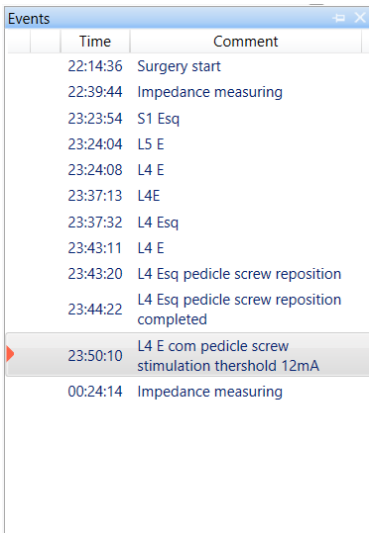
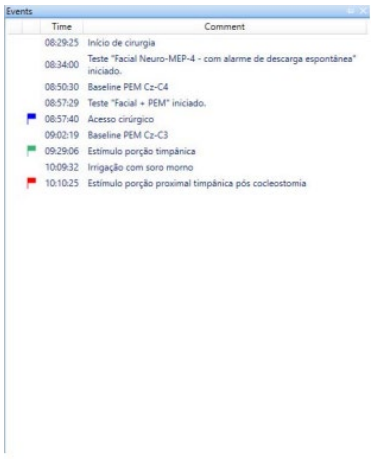
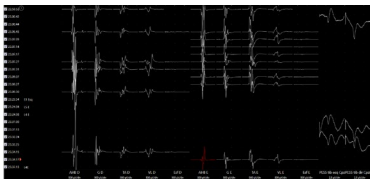
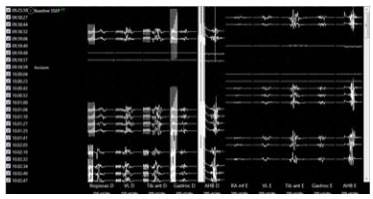
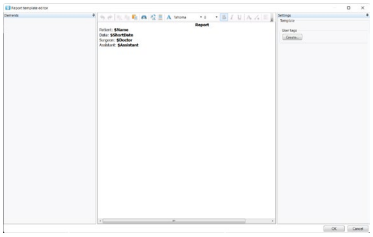
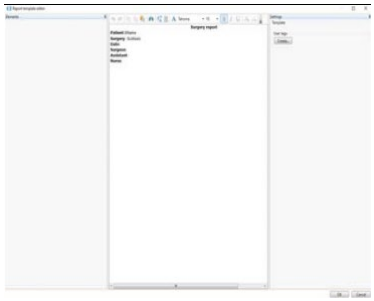
Parameter	MEGA-IOM Subject Device	Neuro-IOM Predicate Device	Comment
Interface to Computer	USB	USB	**Identical**
Channels	16/32	16/32	**Identical**
1.5 mm touch-proof input jacks on pods	Same	Same	**Identical**
Cable Length	5 m	5 m	**Identical**
Input Impedance	>1000 MOhm	>1000 MOhm	**Identical**
Common Mode Rejection (CMRR)	>90 dB	>90 dB	**Identical**
Low Frequency Filters	0.2 Hz - 2000 Hz	0.2 Hz - 2000 Hz	**Identical**
High Frequency Filters	10 Hz - 4 kHz	10 Hz - 4 kHz	**Identical**
Notch Filter	50/60 Hz	50/60 Hz	**Identical**
Sample Rate	50 kHz	50 kHz	**Identical**
Sensitivity	0.05 µV/division to 20 mV/division	0.05 µV/division to 20 mV/division	**Identical**
Noise Level	<0.6 µV (<9.5 nV/√Hz)	<0.6 µV (<9.5 nV/√Hz)	**Identical**
Artifact Rejection	Independent for each channel	Independent for each channel	**Identical**
Number of Channels	16/12/4/4	16/12/4/4	**Identical**
Max Intensity	200 mA	200 mA	**Identical**
Duration	0.02 - 5 ms	0.02 - 5 ms	**Identical**

Parameter	MEGA-IOM Subject Device	Neuro-IOM Predicate Device	Comment
Stimulus Type	Mono-/biphasic	Mono-/biphasic	**Identical**
Electrical Modes	Single, repetitive, trains	Single, repetitive, trains	**Identical**
Transcranial Electrical stimulator Number of Channels Max Intensity Duration	 4 1000 V 0.04 - 0.2 ms	 4 1000 V 0.04 - 0.2 ms	**Identical**
Low current stimulator Number of Channels Max Intensity Duration	 3/2/1 20 mA 0.05 - 0.5 ms	 3/2/1 20 mA 0.05 - 0.5 ms	**Identical**
Stimulation Type	Click, tone, noise	Click, tone, noise	**Identical**
Rate	0.01 - 100 Hz	0.01 - 100 Hz	**Identical**
Intensity	120 dB nHL	120 dB nHL	**Identical**
Polarity	Condensation, rarefaction, alternating	Condensation, rarefaction, alternating	**Identical**
Transducers	Insert earphone EAR-3A-10 Ohms	Insert earphone EAR-3A-10 Ohms	**Identical**
Rate	0.01 - 100 Hz	0.01 - 100 Hz	**Identical**
Color	red	red	**Identical**
SSEP	Yes	Yes	**Identical**
MEP	Yes	Yes	**Identical**
TcMEP	Yes	Yes	**Identical**

Parameter	MEGA-IOM Subject Device	Neuro-IOM Predicate Device	Comment
BAEP	Yes	Yes	**Identical**
VEP	Yes	Yes	**Identical**
EMG	Yes	Yes	**Identical**
EEG	Yes	Yes	**Identical**
Multimodality	Yes	Yes	**Identical**
Predefined test templates	Yes	Yes	**Identical**
Creation and editing of test templates	Yes	Yes	**Identical**
Generation of neuromonitoring report	Yes	Yes	**Identical**
Image review from microscope or other sources	Yes	Yes	**Identical**
Trending	Yes	Yes	**Identical**
ESU Detection	Yes	Yes	**Identical**
Power Supply	220/230 V AC 50/60 Hz	220/230 V AC 50/60 Hz	**Identical**
Visual	LED goggles	LED goggles	**Identical**
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.	**Identical**

Parameter	MEGA-IOM Subject Device	Neuro-IOM Predicate Device	Comment
Freerun waveform			**Identical**
SSEP, AEP, VER (Averaged) waveform			**Identical**
MEP (triggered) waveform			**Identical**
EEG Window			**Identical**

Parameter	MEGA-IOM Subject Device	Neuro-IOM Predicate Device	Comment
CSA Window			**Identical**
DSA Window			**Identical**
Trending Window			**Identical**

Parameter	MEGA-IOM Subject Device	Neuro-IOM Predicate Device	Comment
Log Book Window			**Identical**
History Window			**Identical**
Report Template			**Identical**

Conclusion

The MEGA-IOM device is technologically similar to the predicate device. The differences in the technological aspects are limited to the software modifications that have been made to improve the usability and bugs associated with the software. The hardware and indications for use (IFU) statement are identical to the predicate and no changes have been made therein.

To account for the software changes, nonclinical tests in the form of software verification and validation have been provided to demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device K190703 Neuro-IOM.