5. 510(K) SUMMARY

5.1 Submitter

Date:	August 01, 2014
Name:	Mitsar Co. Ltd.
Address:	Novorossiyskaya str. 21-2 194021 St. Petersburg Russian Federation
Post address:	Politekhnicheskaya str., 6D 194021 St. Petersburg Russian Federation

Contact person in the Russian Federation:	Ales Semchenkov
Telephone:	+7-812-297-90-13
FAX:	+7-821-297-17-33
E-Mail:	aas@mitsar-eeg.ru

Contact person in the U.S.:	Leslie Sherlin
Address:	NOVA TECH EEG, INC. 8503 E. Keats Avenue, Mesa, AZ 85209
Telephone:	(480) 219-3048
FAX:	(419) 858-0407
E-Mail:	lsherlinphd@novatecheeg.com

5.2 Device

Trade Name:	Mitsar-EEG
Common Name:	Full-Montage Standard Electroencephalograph
Regulation Description:	Electroencephalograph
Product Code:	GWQ
Regulation Number:	882.1400
Device Class:	Class II
Classification Panel:	Neurology

5.3 Predicate Devices

510(K) Number	Classification Product Code	Trade or Proprietary or Model Name	Manufacturer
K061908	GWQ	NicoletOne System V32 Amplifier with Oximetery	VIASYS NeuroCare, Inc. (NATUS, Inc.) 5225 Verona Road

			Madison, WI 53711
K946094	GWQ	Cadwell Easy II EEG	Cadwell Laboratories Inc. 909 North Kellogg Street Konnewick, WA 99336

5.4 Device Description

The device Mitsar-EEG is intended to acquire, display and store the electrical activity of a patient's brain obtained by placing two or more electrodes on the head to aid in diagnosis.

The medical device “Mitsar EEG” consists of biosignal amplifier, USB cable, USB dongle and software.

The USB cable is part of the device. It is a standard USB-cable, substantially equivalent to the legally marketed predicates.

The USB dongle is also part of the device. It is a standard security token to authenticate software.

The software is supplied by means of information media and intended for device functioning.

The medical system includes “Mitsar EEG” device and computer (stationary PC with uninterruptible power supply (UPS) or laptop with internal battery). The system may include a medical cart and isolation transformer.

The device does not come in direct contact with patients. Accessories that contact patients, such as electrodes and cap-type electrodes, are the same as used with the legally marketed devices or are comprised of the same components materials as legally marketed accessories. Electrodes and cap-type electrodes are not supplied together with the Mitsar-EEG.

The device is intended for use in functional diagnostics wards and departments at out-patient clinics, hospitals, health research institutes, health centers and other medical institutions. Also, investigations can be performed outside of healthcare facilities, as long as they are led by qualified medical personnel.

The device does not draw any diagnostic conclusion. Recorded data is intended for use as an aid to diagnosis only. No medication or treatment is applied based on this data only. The results have to be considered only in conjunction with other clinical findings.

The device is not sterile. The device is intended for use by qualified medical personnel only and qualifies for exemption per 21 CFR 801 Subpart D «Prescription devices».

Required Components

- EEG amplifier

- USB-cable
- USB dongle
- EEG Studio software
- User manuals

5.5 Indications for use

The Mitsar-EEG is intended to acquire, display and store the electrical activity of a patient's brain obtained by placing two or more electrodes on the head to aid in diagnosis.

Intended use of the Mitsar-EEG is substantially equivalent to the intended use of legally marketed predicate devices.

5.6 Comparison of technological characteristics with the predicate devices

Comparison of Mitsar-EEG and Cadwell Easy II K946094, and NicoletOne System V32 Amplifier with Oximetery K061908. The primary predicate device is NicoletOne System V32 Amplifier with Oximetery.

Channels

The device Mitsar-EEG contains fewer EEG-channels than the predicate devices do. However, according to Minimum Technical Requirements for Performing Clinical Electroencephalography by American Clinical Neurophysiology Society found in the ACNS Guideline 1: “All 21 electrodes and placements recommended by the International Federation of Clinical Neurophysiology (IFCN; Jasper HH, 1958, 1983) should be used”.
It is sufficient for the 10-20 System of electrodes placement officially recommended by IFCN: “The 10-20 System is the only one officially recommended by the IFCN. It is the most commonly used existing system, and it should be used universally.”

Frequency band
Frequency band of Mitsar-EEG (0.16 - 70 Hz) is the same as frequency band of Cadwell Easy II (0,16 - 70 Hz), but more narrow than NicoletOne System V32 (0,053 - 500 Hz). The frequency band 0.16 - 70 Hz is sufficient for registration of EEG.

Input impedance

The input impedance of the device is greater than predicate devices, therefor Mitsar device introduces less distortion in the measured signal.

The difference in this characteristic does not affect the safety of the device.

Noise

The noise level of Mitsar-EEG lower than predicates have therefore the recording on this device will be better.
The difference in this characteristic does not affect the safety of the device.

Offset tolerance

The offset tolerance of the device is greater than predicates, which allows using the device at a high electrode polarization.
The difference in this characteristic does not affect the safety of the device.

The safety class of the Mitsar-EEG is Class II and is equal to safety class of primary predicate device NicoletOne System V32 Amplifier.

Value of sterility, presence of calibration signal, the LED impedance indicators and touch proof connectors are the same for all devices.

The Mitsar-EEG is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use, and performs as well as, or better than the predicate devices.

5.7 Performance data

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

Biocompatibility

The device doesn't come into direct or indirect contact with patients and it supplied without electrodes.

Electrical safety and electromagnetic compatibility (EMC)

The tests have been performed by the accredited laboratories and show full compliance with standards below.

The device under consideration has passed the tests according to IEC 60601-1.

Analysis of deviations from IEC 60601-1:2005 in ANSI/AAMI ES60601-1:2005 do not affect safety or effectiveness of the system «Mitsar-EEG». Therefore, the conformation with ANSI/AAMI ES60601-1:2005 can be declared.

The device under consideration has passed the tests according to IEC 60601-1-2 and IEC-60601-2-26.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, «Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices» and «General Principles of Software Validation».

Mechanical and acoustic testing

Push test, Impact test, Drop test according to IEC 60601-1.

Animal Study

This submittal does not include data on animal testing. Therefore, this section is not applicable.

Clinical Studies

Clinical studies were not required to demonstrate that this device is at least as safe and effective as the identified predicate device.

5.8 Conclusions

Based on the above, Mitsar Co. Ltd. concludes, that Mitsar-EEG is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use, and performs as well as, or better than, the predicate devices.