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

August 13, 2015

Mitsar Co., LTD
c/o Leslie Sherlin
Nova Tech EEG
8503 E. Keats Avenue
Mesa, AZ 85209

Re: K143233
Trade/Device Name: Mitsar-EEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: May 7, 2015
Received: July 16, 2015

Dear Dr. Sherlin:

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 [**SELECT ONE:** Part 801 **[or, for IVDs only]** Parts 801 and

809]); 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 Industry and Consumer Education 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 Industry and Consumer Education 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 FDA

Carlos 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 below.

510(k) Number *(if known)*
K143233

Device Name
Mitsar-EEG

Indications for Use *(Describe)*
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.

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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5. 510(K) SUMMARY

5.1 Submitter

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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.