February 16, 2018

MemoryMD Inc.
Abdus-Salaam Muwwakkil
Chief Quality Officer
205 East 42nd St 14th FL
New York, New York 10017

Re: K173460
Trade/Device Name: NeuroEEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: November 6, 2017
Received: November 21, 2017

Dear Abdus-Salaam Muwwakkil:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173460

Device Name
NeuroEEG

Indications for Use *(Describe)*
NeuroEEG is intended for prescription use to acquire, record, transmit, and display electrical brain activity of patients of all ages.

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."

K173460

510(k) Summary

Identification of Submitter	
Primary Contact Name	Abdus-Salaam Muwwakkil, Chief Quality Officer MemoryMD Inc.
Address:	205 E 42nd Street, 14th Floor New York, New York 10017, USA
Telephone:	215-341-6373
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Email:	abdus@memorymd.com
Name / Address of Manufacturer:	MemoryMD Inc. 67 35th street, c250 Brooklyn, New York 11232, USA
Date Prepared	**11/06/2017**
Identification of the subject device	
Device Proprietary Name:	NeuroEEG
Common Name:	Full-Montage Standard Electroencephalograph
Regulation:	21 CFR 882.1400
Review Panel:	Neurology
Product Code:	GWQ
Classification Panel:	Neurology
Device Class:	Class II

Predicate Device			
510(k) Number	**Classification Product Code**	**Trade of Proprietary**	**Manufacturer**
K150498	GWQ	Discovery 24	Brainmaster Technologies, Inc. 195 Willis Street, Suite 3 Bedford, OH 44146

Device Description
"NeuroEEG" is a 16-lead electroencephalograph. Electrodes correspond to the international 10-20 standard. It is a portable, non-sterile, non-invasive, non-radiation emitting electroencephalogram (EEG) device that works with a stationary PC with uninterruptible power supply (UPS) or a laptop with an internal battery.

Signal transfer occurs between NeuroEEG and PC via wireless Bluetooth channel. The accompanying MemoryMD software runs on the Windows operating system (OS) Windows 8.1 and later.

This device will be used "By Prescription" pursuant to 21 CFR 801 Subpart D. The medical use of data acquired by "NeuroEEG" is to be performed under the direction and interpretation of a licensed medical professional. This device does not provide any diagnostic conclusion about a subject's condition.

The generated data serves as an assessment aid at medical practices, rehabilitation institutions, diagnostic centers, neurosurgical clinics, OR, ICU, ER, and clinical research institutes.

The device consists of the following components:

- Registration Module;
- Bluetooth Adapter
- Charger and USB Cable
- Connection cable of electrode system NeuroCap
- Connection cable of electrode system StatNet
- Cuff;
- Flash Card;
- Flash Card Reading Device;
- Software Flash Disk with Software Description
- User's Guide

Intended Use of Device
NeuroEEG is intended for prescription use to acquire, record, transmit, and display electrical brain activity of patients of all ages.

Test Summary
Electrical safety and electromagnetic compatibility (EMC) tests have been performed by the accredited laboratories and show full compliance with the standards below. The device under consideration has passed the tests according to (FDA recognition number – standard designation number):

- **19-4 –** AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

- **19-12 –** IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

- **5-89 –** IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability

- **19-16 –** IEC 60601-1-11 Edition 2.0 2015-01, Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment

- IEC 60601-2-26:2012 (Third Edition): Particular requirements for the basic safety and essential performance of electroencephalographs

- FCC Part 15: 2015 Subpart B

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". Verification and Validation activities have been successfully performed on the software package, including assurance that functions work as designed, performance requirements and specifications have been met, and that all hazard mitigations have been fully implemented. All testing has met the predetermined acceptance values. Traceability of the requirements specified in the requirement specifications and functional specifications is ensured during component integration, software validation and system testing.

The device under consideration has passed the test according to (Recognition Number – standard):

- **13-79**: IEC 62304 Edition 1.1 2015-06, Medical Device Software - Software Life Cycle Processes.

Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the proposed NeuroEEG is substantially equivalent to the predicate device quoted below. The differences between the subject device and predicate device does not raise new issues of safety or effectiveness.

	Discovery 24E **K150498**	"NeuroEEG" by MemoryMD **K173460**
MODALITIES	EEG	EEG

INDICATION FOR USE	Indicated for prescription use to acquire, record and display physiological and data for electroencephalograph studies of patients of all ages	NeuroEEG is intended for prescription use to acquire, record, transmit, and display electrical brain activity of patients of all ages.
SYSTEM COMPONENTS	Hardware Module; Brain Avatar Acquisition software; Electrode cap (sold separately); USB Cable w/chokes; Touch-Proof sockets that allow use of compliant "free sensors' without a cap	Registration Module, Bluetooth adapter, Charger and USB Cable, Connection cable of electrode system Neuro Cap connection, Connection cable electrode system StatNet, Cuff, Flash card, Flash Card Reading Device, Software Flash Disk with Software description, User's Guide
# OF EEG CHANNELS	24	16
A/D RESOLUTION	24 bit	24 bit
DIGITIZATION RATE	1024 Hz	500 Hz
SAMPLING RATE	256 Hz	500 Hz
IMPEDANCE CHECK	Yes	Yes
BATTERY CHARGE CURRENT	n/a	400 mA
WIRELESS CONNECTION CHANNEL FREQUENCY	n/a	2.4 GHz
ENVIRONMENT FOR USE	Clinical EEG	Clinical and experimental EEG; laboratory research; Rehabilitation centers; OR, ICU, ER
SOFTWARE	BrainAvatar	MemoryMD
PATIENT ISOLATION	optical & magnetic	No connection of the product to the power supply or PC during the registration.
ISOLATION VOLTAGE	>2500V	No connection of the product to the power supply or PC during the registration.

Connection to PC	USB, optically and magnetically isolated	Bluetooth
NOTCH FILTERING	60/50 Hz	100/60/50 Hz
COMMON MODE REJECTION RATIO	>120 dB	>110 dB
GAIN	16	6
INPUT IMPEDANCE	> 1000GOhms	min 1GOhms
INPUT NOISE	1.5uV at input	Less than 2 uV
SELF-Calibration	Yes	Yes
FREQUENCY BAND	0.5 - 70 Hz	0 - 80 Hz
Input Range	100 mV p-p	±0.8V
Amplifier bandwidth	0.000 - 100 Hz	0 – 125 Hz
A/D accuracy	24 bits; resolution 0.01 microvolts EEG, 0.4 microvolts DC	24 bits; resolution 0.1 microvolts EEG, 0.1 microvolts DC
Power	Isolated Power via USB port	Internal battery
Shelf Life	n/a	5 years

The “NeuroEEG” device is similar in intended use, operating principals and fundamental scientific technology to the following predicate device: “Discovery 24” (K150498: Date of Premarket Notification Approval: January 26, 2016).

As shown in the table below, both systems have the same manner of use, being computer-based digital EEG systems with basic functions. They have similar requirements for training and expectations of user. The safety requirements and expectations are the same. The systems have comparable performance in terms of data sampling, accuracy, speed and resolution of displays. They use identical patient connectors and methodology, being standard 10-20 EEG sensor placement.