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

January 26, 2016

Brainmaster Technologies, Inc.
% Ms. Maria Griffin
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd. Suite 200
Great Neck, New York 11021

Re: K150498
Trade/Device Name: Discovery 24
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: December 1, 2015
Received: December 4, 2015

Dear Ms. Griffin:

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.

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" (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.

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,

Michael J. Hoffmann -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150498

Device Name
Discovery 24

Indications for Use *(Describe)*
Indicated for prescription use to acquire, record, transmit, and display physiological and data for electroencephalograph studies 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

The assigned 5l0(k) number is:_____.

1. Submitter's Identification:

Brainmaster Technologies, Inc.
195 Willis Street, Suite 3
Bedford, OH 44146

Contact Person: Tom Collura, President
Tel: 440-232-6000 ext. 205

Date Summary Prepared: January 25, 2016

2. Trade Name of the Device:

BrainMaster™ Discovery 24

3. Common or Usual Name: full-montage standard electroencephalograph

4. Classification:

Regulation: 21 CFR 882.1400
Product Code: GWQ

5. Predicate Device Information: The Vanguard System, k941551

6. Device Description:

The BrainMaster™ Discovery 24 are two-channel, four- channel, and 24-channel electrophysiological acquisition and biofeedback devices.

The 24-channel (Discovery 24) digital EEG devices use industry-accepted Windows-based PC as the control and display console. The devices consist of the following:

1. BrainMaster™ Discovery 24 Hardware Module
2. BrainMaster™ software – BrainMaster™ BrainAvatar Acquisition software
3. Electrocap, which is sold separately.
4. The system also includes a full set of DIN-compliant touch-proof sockets, either on the main housing, or in an accessory cable, that allows the use of compliant sensors for use of “free sensors” without a cap.

These products are designed for use with a standard IBM PC/AT compatible computers (Windows 7 and later) and associated peripheral equipment such as keyboard, mouse, and monitor(s). When assembled with a computer, the BrainMaster™ Discovery 24 system will acquire EEG and display and save it to disc.

7. Intended Use:

Indicated for prescription use to acquire, record, transmit, and display physiological and data for electroencephalograph (EEG) studies of patients of all ages.

8. Technological Comparison to Predicate Devices:

PRODUCT	Cleveland Clinic Vanguard System	BrainMaster Discovery 24
SCROLLED LIVE EEG	yes	yes
SYNCH VIDEO/EEG	yes	no
ADJUSTABLE VIEW	yes	yes
ADJUSTABLE VIEW DURATION	yes	yes
ONSCREEN MARKERS	yes	yes
DIGITAL FILTERING	yes	yes
MONTAGE EDITOR	yes	yes
REMOTE SCREEN VIEW	yes	yes
POWER	CPU (EISA) bus	Isolated Power via USB port
# OF EEG CHANNELS	32-64	24
A/D RESOLUTION	12 bits	24 bit
DIGITIZATION RATE	200 Hz	1024 Hz
SAMPLING RATE	200 Hz	256 Hz
IMPEDANCE CHECK	Yes	Yes
INDICATIONS FOR USE	Clinical EEG	Clinical EEG
SOFTWARE	EMach	BrainAvatar
PATIENT ISOLATION	optical	optical & magnetic
ISOLATION VOLTAGE	>2500V	>2500V
INTERFACE	EISA bus	USB
NOTCH FILTERING	60/50 Hz	60/50 Hz
COMMON MODE REJECTION RATIO	>110 dB	>120 dB
GAIN	1000	16
INPUT IMPEDANCE	>100MOhm	>1000GOhm
INPUT NOISE	1.5uV at input	1.5uV at input
SELF-CAL	yeses	yes
FREQUENCY RANGE	0.5 - 70 Hz	0.5 - 70 Hz
Input Range	1250 uV p-p	100 mV p-p

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following non-clinical tests were performed to support the determination of substantial equivalence;

IEC 60601-1-2 Ed. 3: 2007 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-26 Ed. 3.0 B: 2012 Medical Electrical Equipment Part 2-26: Particular Requirements for the Basic Safety and Essential Performance of Electroencephalographs

Software Validation Testing per approved procedures

The devices passed all testing.

10. Discussion of Clinical Tests Performed:

Not applicable.

11. Discussion of Substantial Equivalence

The BrainMaster system has the same intended use in the same environments as the predicate device. It has the same manner of use, being a computer-based digital EEG system with basic functions, and it has a similar requirement for training and expectations of user. The safety requirements and expectations are the same. The systems have comparable performance in terms of data sampling and accuracy, and speed and resolution of displays. They use identical patient connectors and methodology, being standard clinical EEG sensor placement.

12. Conclusions:

Based on the information provided in this submission we conclude that BrainMaster™ Discovery 24 is substantially equivalent to the predicate and are safe and effective for its intended use.