July 1, 2018

BrainMaster Technologies, Inc.
% Maria F. Griffin
Senior Consultant
mdi Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K171414
Trade/Device Name: qEEG-Pro
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLU
Dated: April 11, 2017
Received: May 15, 2017

Dear Maria F. 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.

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 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,

Jay R. Gupta -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)*
K171414

Device Name
qEEG-Pro

Indications for Use *(Describe)*
The qEEG-Pro System is to be used by qualified medical or qualified clinical professionals for the statistical evaluation of the human electroencephalogram (EEG).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K171414
510(k) SUMMARY

I. SUBMITTER

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

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

Date Prepared: June 29, 2018

II. DEVICE

Name of Device: qEEG-Pro
Common Name: Normalizing Quantitative Electroencephalograph Software
Classification Name: Electroencephalograph
Regulatory Class: II
Product Code: OLU

III. PREDICATE DEVICE

NeuroGuide Analysis System (NAS), K041263

IV. DEVICE DESCRIPTION

qEEG Pro Database (QPD) is a software program for the post-hoc statistical analysis of the human electroencephalogram (EEG). EEG recorded on a separate device (i.e., the host system) is transferred to the QPD for display and user-review. The device herein described consists of a set of tables that represent the reference means and standard deviations for representative samples. These tables are implemented as computer files that provide access to the exact tabular data resource for use by software that uses the tables as an information resource. The system requires that the user select reliable samples of artifact-free, eyes-closed or eyes open, resting digital EEG for purposes of analysis.

Analysis consists of the Fast-Fourier Transformation (FFT) of the data to extract the spectral power for each of the designated frequency bands (e.g. delta, theta, alpha, and beta), and frequency information from the EEG. The results of this analysis are then displayed in statistical tables and topographical brain maps of absolute and relative power, power asymmetry, and coherence for 19 monopolar and 171 selected bipolar derivations of the EEG. In all over 5,000 measures are derived for comparison against

carefully constructed and statistically controlled age-regressed, normative database in which the variables have been transformed and validated for their Gaussian distribution.

Each variable extracted by the analysis is compared to the database using parametric statistical procedures that express the differences between the patient and an appropriate age-matched reference group in the form of z-scores.

V. INDICATIONS FOR USE

The qEEG-Pro System is to be used by qualified medical or qualified clinical professionals for the statistical evaluation of the human electroencephalogram (EEG).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

Item	**qEEG-Pro**	**NeuroGuide Analysis System (NAS) K041263**
Indications for Use	The qEEGpro system is to be used by qualified medical and qualified clinical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG). Rx-only	The NAS system is to be used by qualified medical and qualified clinical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG). OTC
EEG data comparison against normative database	Yes; 1482 samples (eyes-closed);1231 subjects (eyes-open)	Yes; 625 samples
EEG Spectral Analysis	Yes; 4 frequency bands (delta, theta, alpha, and beta)	Yes; 4 frequency bands (delta, theta, alpha, and beta)
Age Range Included in the Normative Database	4-82 years	2 months-82 years
Product code	OLU	OLU
Classification	882.1400	882.1400
Visual Display of EEG	Yes	Yes
Software	Proprietary via DLL	Proprietary via DLL

VII. PERFORMANCE DATA

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

Non-Clinical Testing

Software documentation up to a moderate level of concern was submitted which included validation performance testing. Non-clinical performance testing included delta, theta, alpha, and beta comparison of the subject and predicate device using a variety of simulated signals which were analyzed for frequency and power. These performance data demonstrated confirmation by examination of pre-specified, objective evidence to specify that output requirements for the software have been fulfilled and met through static and dynamic analyses and code and document inspections. The software testing performance data further established that the software device's specifications consistently conform to the pre-specified user needs and the intended use. The algorithms and statistical methods used for data analysis were also evaluated through these tests. Therefore, the testing demonstrated the that the system accurately translates and presents EEGs from patients.

Potential adverse effects of the use of the device are known if the qEEG-Pro is used as a stand-alone diagnostic system in the absence of other clinical data from more traditional means of patient evaluation. Relying only upon the use of a single index (such as relative power or the topological maps alone) without reviewing the traditional EEG, the epochs selected for analysis, or the complete set of statistical summary tables is also contraindicated and a source of potential error. Additional sources of error could arise from the inappropriate selection of EEG (selecting artifacted EEG epochs, or selecting EEG representative of other states, such as drowsiness or eyes-open EEG when comparing to an eyes-closed database, or by purposely selecting conditions for testing other than those specified. Additionally, it is possible that errors will occur through the purposeful falsification of symptoms in the patient history and patient age.

Clinical Testing

Clinical testing of the subject device included a study of 3 subjects who were used to validate performance of subject device database to that of the predicate K041263. These subjects were adequate to provide a range of values of the databases to verify performance since they are part of the adult and pediatric range of ages as well as the frequencies within the databases. Acceptance criteria were defined as the qEEG-Pro produces results sufficiently in agreement with the predicate devices and that the R-squared factor shall be 0.8 or better. Additionally, the observed range of results obtained from the predicate devices shall be used to verify that the qEEG-Pro produces results in agreement with the results obtained from the predicate device. The pre-defined acceptance criteria were met as 9-minute EEG recordings for eyes closed and open of the subjects (1 pediatric 9 years, 2 adult 48 and 46 both male and female) were de-artifacted and used to calculate z-scores for absolute power for the subject and predicate databases. Although the sample size was small, it was possible to validate results by computing values for all discrete ages ranging between 6 and 60, resulting in 55 sets of z-scores for each subject's EEG sample which were compared with the predicate device's output and found to also be similar.

VIII. CONCLUSIONS

The qEEG-Pro has the same intended use as the predicate device, and it has the same manner of use and function, being a software-based database. Furthermore, it has similar requirements for training and expectations of intended users. The systems have equivalent performance in terms of data sampling and accuracy in the reference norms across age. Based on the device

description, IFU, and performance testing, the qEEG-Pro is substantially equivalent to the predicate.