January 28, 2023

Medeia, Inc.
% Daniel Lehtonen
Regulatory Consultant
Compliance and Regulatory Services, LLC
3771 Southbrook Dr.
Dayton, Ohio 45430

Re: K212684
Trade/Device Name: BrainView QEEG Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLU
Dated: February 4, 2022
Received: February 8, 2022

Dear Daniel Lehtonen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212684

Device Name
BrainView QEEG Software Package

Indications for Use *(Describe)*
The BrainView QEEG Software Package is to be used by qualified medical or 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.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the Requirements of Safe Medical Device Systems Act 1990 and 21 CFR Sec. 807.92

510(k) Number: **K212684**

a1 APPLICANT INFORMATION:

Date Prepared: 10 Dec 2021

Name: Medeia, Inc.

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Suite 300
Santa Barbara, CA, 93101

Contact Person: Slav Danev

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a2 NAME OF DEVICE:

Trade Name: BrainView QEEG Software Package

Common Name: Normalizing Quantitative Electroencephalograph Software

Classification Name: Electroencephalograph; 21 CFR 882.1400 (OLU)

Classification Panel: Neurology

a3 PREDICATE DEVICES:

Predicate Device: K041263; NeuroGuide Analysis System (NAS)

Reference Device: K171414; qEEG-Pro

The FDA database for recalls was searched on 03 March 2021 during the preparation of the 510(k) submission and no recalls for the devices noted above were found.

a4 STATEMENT OF INTENDED USE:

The BrainView QEEG Software Package is to be used by qualified medical or clinical professionals for the statistical evaluation of the human electroencephalogram (EEG).

a5 DESCRIPTION OF THE DEVICE:

BrainView QEEG Software Package 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 BrainView QEEG software package 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 4,000 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.

The BrainView QEEG Software Package is intended for prescription use by qualified medical personnel.

The device is intended for use by qualified medical personnel only and qualifies for exemption per 21 CFR 801 Subpart D Prescription devices.

a6 TECHNOLOGICAL CHARACTERISTIC COMPARISON:

Item	**BrainView QEEG**	**NeuroGuide Analysis System (NAS) K041263**	**qEEG-Pro K171414**
Device	Subject Device	Predicate Device	Reference Device
Indications for Use	The BrainView QEEG 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	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
EEG data comparison against normative database	Yes; 2303 subjects (eyes closed); 1965 subjects (eyes open)	Yes; 625 samples	Yes; 1482 samples (eyes closed); 1231 subjects (eyes open)
EEG Spectral Analysis	Yes; 4 frequency bands (delta, theta, alpha, and beta)	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	4-85 years	2 months-82 years	4-82 years
Product code	OLU	OLU	OLU
Classification	882.1400	882.1400	882.1400
Visual Display of EEG	Yes	Yes	Yes
Software	Proprietary via DLL	Proprietary via DLL	Proprietary via DLL
Software Features	Onscreen QEEG Z-Scores and maps	Onscreen QEEG Z-Scores and maps	Onscreen QEEG Z-Scores and maps
Frequency Range	1 - 40 Hz	0.5 to 40 Hz	1 - 40 Hz
Ratio of power	Yes	Yes	Yes

b1 NON-CLINICAL 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 BrainView QEEG software package is used as a standalone 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 EEG epochs with artifacts, 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.

Referenced Standards and Performance Testing:
The BrainView QEEG Software Package was developed using:

- IEC 62304:2015 [Edition 1.1] Medical device software — Software life cycle processes

<u>Software Verification and Validation Testing</u>
Software verification and validation testing were conducted following the FDA guidance document for software contained in medical devices. The software was considered to be a "moderate" level of concern since a failure or latent flaw could indirectly result in a minor injury to the patient through incorrect or delayed information or through action of the operator.

b2 CLINICAL TESTING:

Clinical testing of the subject device included the use clinically acquired EEG waveforms from selected 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 BrainView QEEG software produces results sufficiently in agreement with the predicate device and that the R-squared factor shall be 0.8 or better. Additionally, the observed range of results obtained from the predicate device shall be used to verify that the BrainView QEEG produces results in agreement with the results obtained from the predicate device. The pre-defined acceptance criteria were met as 10-minute EEG recordings for eyes closed and eyes open of the subjects 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 4 and 85, resulting in 23 age grouped sets of Z-scores for each subject's EEG sample which were compared with the predicate device's output and found to be similar.

b3 CONCLUSIONS:

The BrainView QEEG software 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 BrainView QEEG software package is substantially equivalent to the predicate.