December 7, 2020

elminda, Ltd
% Donna-Bea Tillman
Senior Consultant
Biologics Consulting
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K202588
Trade/Device Name: BNA Platform
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLU
Dated: September 4, 2020
Received: September 8, 2020

Dear Donna-Bea Tillman:

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 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)*
K202588

Device Name
BNA™ Platform

Indications for Use *(Describe)*
The BNA™ Platform is to be used by qualified medical professionals for the post-hoc statistical analysis of the human electroencephalogram ("EEG"), including event-related potentials ("ERPs').
This device is indicated for use in individuals 12 to 85 years of age.
The BNA™ Platform is to be used with the Auditory Oddball, Visual Go No-Go (age range of 25 to 85 years), and Eyes-Closed tasks.

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."

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the BNA™ Platform is provided below.

1. SUBMITTER

Applicant:	elminda Ltd. 1 Arie Shenkar Street Herzliya, 4672501, Israel
Contact:	Keren Elghouzzi-Kazachinsky QA/RA Manager Elminda +972-53 7739780 quality@elminda.com
Submission Correspondent:	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consulting 1555 King St, Suite 300 Alexandria, VA 22314 410-531-6542 dtillman@biologicsconsulting.com
Date Prepared:	December 3, 2020

2. DEVICE

Device Trade Name:	BNA™ Platform
Device Common Name:	Normalizing Quantitative Electroencephalograph Software
Classification Name	21 CFR 882.1400 Electroencephalograph,
Regulatory Class:	II
Product Code:	OLU

3. PREDICATE DEVICE

Predicate Device:	K121119 - BNA™ Analysis System (Elminda)
Secondary Predicate Device:	K171414 - qEEG-Pro (BrainMasters Technologies, Inc)

4. DEVICE DESCRIPTION

The BNA™ Platform is intended for the post-hoc statistical analysis of the human electroencephalogram ("EEG"), utilizing both resting-state EEG and Event-Related Potentials ("ERP") in a patient's response to outside stimuli during various states of alertness, disease, diagnostic testing, treatment, surgery, or drug related dysfunction. An Event-Related Potential (or "evoked response") is an electrical potential recorded from the nervous system following the presentation of a stimulus (e.g., as part of a cognitive task). An ERP signal consists of typical ERP components - positive or negative voltage spatiotemporal peaks within the ERP waveform that are measured within one second post-stimulus presentation. The BNA™ Platform is intended to analyze EEG data recorded at rest and during the performance of two conventionally used ERP tasks, the Auditory Oddball (AOB) and the Visual Go No-Go (VGNG).

The EEG is recorded continuously while the patient is at rest with eyes-closed (hereby Eyes-Closed) or performs one of the ERP tasks (hereby ERP tasks). The acquisition site is asked to provide reliable samples of artifact-free digital EEG for purposes of analysis. After the recording, the artifact-free EEG data is imported into the BNA™ Platform and is automatically analyzed by the algorithm and the results of the processed data are compiled into individualized Reports:

- ERP Report
- Behavioral Report
- Summary Report
- Resting-State EEG Report

Scores are presented as Z-Scores based on comparing the patient to an age-matched relevant reference group based on elminda's normative database. This presentation expresses the differences between the patient and the reference group.

The BNA™ Reports are intended to be used by clinicians to enable the evaluation of the patient's brain activity during a specific task compared to an age-range matched reference group.

.

The system consists of the following components: a computer environment; EEG data input software algorithms for BNA™ calculations; a report generator and a functionality for data transfer and storage.

The device processes and analyzes data received from a dedicated, commercially available, and FDA cleared EEG system, which complies with the BNA™ Platform specifications.

5. INTENDED USE/INDICATIONS FOR USE

The BNA™ Platform is to be used by qualified medical professionals for the post-hoc statistical analysis of the human electroencephalogram ("EEG"), including event-related potentials ("ERPs").

This device is indicated for use in individuals 12 to 85 years of age.

The BNA™ Platform is to be used with the Auditory Oddball, Visual Go No-Go (age range of 25 to 85 years), and Eyes-Closed tasks.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

The subject device and the two predicate devices all have the same intended use, namely, to provide analyses of human EEG data. The features of the subject device have been expanded from those of the primary predicate BNA device to include additional age ranges and tasks, similar to the capabilities of the predicate qEEG-Pro device. The differences in the wording of the Indications for use reflect this expansion in features as well as a minor modification to reflect a change to the currently accepted terminology of "event-related potentials" as opposed to "evoked response potentials". These differences do not impact the intended use, and therefore the subject device has the same intended use as the predicate device.

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device K121119 - BNA™ Analysis System (K121119) and qEEG-Pro (K171414).

Table 1: Technological Comparison

	BNA™ Platform Subject Device	**BNA™ Analysis System** Primary Predicate Device	**qEEG-Pro** Secondary Predicate Device	**Discussion**
Manufacturer	elminda	elminda	BrainMasters Technologies, Inc	N/A
510k Number	N/A	K121119	K171414	N/A
Product Code	OLU	OLU	OLU	Same as Predicate
Intended patient population	12-85 years (for AOB and Eyes closed tasks) 25-85 years (for VGNG)	14-24 years	4-82 years	Extended age range; Clinical data demonstrates equivalent performance.
Tasks	AOB, VGNG, and Eyes-Closed Resting-State	Auditory Oddball (AOB)	Eyes-Closed and Eyes-Open Resting-State	Additional Tasks: VGNG and Resting-State EEG; clinical testing demonstrates equivalent in safety and effectiveness.
Intended User	Used by a Clinician / Prescription device	Used by a Clinician / Prescription device	Used by a Clinician / Prescription device	Same as predicate

	BNA™ Platform Subject Device	**BNA™ Analysis System** Primary Predicate Device	**qEEG-Pro** Secondary Predicate Device	**Discussion**
Band Passing (ERP)	Frequency decomposition of the EEG data into: Delta, Theta and Alpha frequency bands.	Frequency decomposition of the EEG data into: Delta, Theta and Alpha frequency bands	Not relevant – does not cover ERP functions	Same as Predicate
Time-Analysis (ERP)	A time domain peak analysis is performed	A time domain peak analysis is performed	Not relevant (ERP only)	Same as predicate
Analysis of Band-passed (ERP)	Peak analysis is applied for the individual band-passed time-series (i.e., peak analysis for Alpha, Delta, Theta)	Peak analysis is applied for the individual band-passed time-series (i.e., peak analysis for Alpha, Delta, Theta)	Not relevant (ERP only)	Same as Predicate
Peak Analysis (ERP)	Peak-detection at the level of the decomposed ERP (post frequency decomposition) is performed for each electrode separately followed by selection of the highest peak.	Peak-detection at the level of the decomposed ERP (post frequency decomposition) is performed for each electrode separately in a specific time and space range	Not relevant (ERP only)	Performance testing demonstrates correct implementation. The results of poolability and normality performance validation test demonstrated equivalence to the success rate of predicate and do not raise new issue of safety and effectiveness
Neural-Consistency	The algorithm calculates a new score – 'Neural Consistency' based on the similarity of the amplitude activation between single-ERP trials	No; new score	Not relevant (ERP only)	Performance testing demonstrates correct implementation. The results of poolability and normality performance validation test demonstrated equivalence to the success rate of predicate and do not raise new issue of safety and effectiveness
Reported ERP peaks	The highest ERP peaks within literature-based time constraints, which show the highest spatio-temporal similarity to the	The ERP peaks at network-based, pre-defined electrodes appear in the report	Not relevant (ERP only)	Performance testing demonstrates correct implementation. The results of poolability and normality performance validation test demonstrated

	BNA™ Platform Subject Device	**BNA™ Analysis System** Primary Predicate Device	**qEEG-Pro** Secondary Predicate Device	**Discussion**
	group ERP appear in the report			equivalence to the success rate of predicate and do not raise new issue of safety and effectiveness
Network Analysis	No network analysis	Network analysis based on the ERP-peaks as the network nodes	Not relevant (ERP only)	Feature removed
Topographical maps of ERP	Subject ERP-peak position is displayed on a topographical map together with the group ERP-peak position.	Z-scores are presented as topographical-maps (electrode coordinates). Networks activity over time is presented in time evolution maps	Not relevant (ERP only)	Performance testing demonstrates correct implementation. The results of poolability and normality performance validation test demonstrated equivalence to the success rate of predicate and do not raise new issue of safety and effectiveness
ERP Waveforms	Broadband (0.5-30Hz) and band-pass (Delta, Theta and Alpha) ERP waveforms of the subject are visualized in comparison to the averaged ERP waveform of the age-matched reference group.	Broadband (0.5-30Hz) ERP waveforms of the subject are visualized in comparison to the averaged ERP waveform of the age-matched reference group.	Not relevant (ERP only)	Performance testing demonstrates correct implementation. The results of poolability and normality performance validation test demonstrated equivalence to the success rate of predicate and do not raise new issue of safety and effectiveness
ERP waveforms display by stimulus type	The ERP waveform display is divided into sections by stimulus type	The ERP waveform display is divided into sections by stimulus type	Not relevant (ERP only)	Same as Predicate
Display of representative ERPs	Within each stimulus-section, 19 panels represent 19 selected electrode locations on the scalp. These are electrode positions described in the international 10-20	Within each stimulus-section 20 panels represent 20 selected electrode locations on the scalp. These are electrode positions described in the international 10-20	Not relevant (ERP only)	Performance testing demonstrates correct implementation.

	BNA™ Platform Subject Device	**BNA™ Analysis System** Primary Predicate Device	**qEEG-Pro** Secondary Predicate Device	**Discussion**
	system of electrode placement.	system of electrode placement.		
Comparison to Normative Database	Yes; 1900 and 1407 subjects covering the age-range 12-85 for the tasks AOB and Eyes-Closed Resting-State EEG, respectively. In addition, 1005 subjects covering the age-range 25-85 for the VGNG task	Yes; 120 subjects in the age-range 14-24 AOB task only	Yes: Z-scores are calculated based on reference-group mean and std. (Not for ERP)	Reference database expanded to include additional subjects; performance testing demonstrates validity of revised database
Resting-State EEG data Comparison against the Normative Database	Yes; 1407 subjects covering the age-range 12-85 for Eyes-Closed Resting-state EEG	No	Yes; 1482 samples (eyes-closed); 1231 subjects (eyes-open)	Clinical data demonstrates equivalent performance
Resting-State EEG Spectral-Analysis	Yes; 4 frequency bands (delta, theta, alpha, and beta)	No	Yes; 4 frequency bands (delta, theta, alpha, and beta)	Same as predicate
Spectral Analysis scores	Yes, the following scores are extracted from PSD: Average Absolute Power, Relative Power, Individual Alpha Frequency, Hemispheric Asymmetry and Frequency Ratios	No	Yes; The following scores are extracted from PSD: Absolute Power, Relative Power, Alpha Peak Frequency, Hemispheric Asymmetry, Coherence and Frequency Ratios	The Average Absolute Power score is well-known in the scientific literature and was statistically validated for normality.
Age Range Included in the Normative Database	12-85 years	14-24 years	4-82 years	The existing normative database has been extended to include additional age-ranges. The additional age-bins and tasks were clinically validated.

	BNA™ Platform Subject Device	**BNA™ Analysis System** Primary Predicate Device	**qEEG-Pro** Secondary Predicate Device	**Discussion**
Visual Display of EEG	Yes: topographical maps of Average Absolute and Relative Power, Individual Alpha Frequency, Hemispheric Asymmetry and Frequency Ratios	No	Yes: topographical maps of Absolute and Relative Power, Power Asymmetry, and Coherence for 19 monopolar and 171 selected bipolar derivations of the EEG	The features are equivalent and the results of performance testing demonstrate equivalent performance
Hardware	Runs on the AWS cloud and accepts EEG data from all sites	Standalone computer running the BNA™ engine locally and contains the EEG/ERP data locally		The results of System and Software Test Verification demonstrate that the subject device meets the defined requirements

In conclusion, the differences in technological characteristics do not raise new questions of safety and effectiveness and the BNA™ Platform can be found substantially equivalent to the predicate devices.

7. PERFORMANCE DATA

Biocompatibility Testing

BNA™ Platform is a software only device. There are no direct or indirect patient-contacting components of the subject device. Therefore, patient contact information is not needed for this device.

Sterilization and Shelf Life

BNA™ Platform is a software only device. Therefore, sterilization and shelf life are not applicable.

Electrical safety and electromagnetic compatibility (EMC)

Not applicable. BNA™ Platform is a software only device. The device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

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." The software for this

device was considered as a moderate level of concern. Testing was conducted to ensure the product works as designed and to validate the performance of the device.

Bench Testing

Not applicable. Bench testing was not necessary to establish the substantial equivalence of this device.

Animal Testing

Not applicable. Animal studies were not necessary to establish the substantial equivalence of this device.

Clinical Data

The objective of the clinical study was to establish and validate the Reference-Group Database and to evaluate its test-retest reliability.

Healthy volunteers aged 12-85 years old were recruited from 13 clinical sites, with 12 sites located within the US. Depending on the site's protocol, the volunteers either participated at a single visit, or at two successive visits, separated by approximately 1 week to provide data for the re-test database. Brain electrophysiological activity was collected using the BNA^{TM} Platform while the participants performed the Eyes-Closed (EC) task and one or more cognitive task, including the Auditory Oddball (AOB) task (using the hearing adjusted version for participants older than 50 years) and the Visual Go-No-Go (VGNG) task.

The Reference-Group Database for the AOB and VGNG tasks is divided into the following age groups: 25-35, 35-50, 50-65, 65-75, and 75-85 years for VGNG, and 12-14, 14-16, 16-18, 18-25, 25-35, 35-50, 50-65, 65-75, and 75-85 years for AOB. For the Resting-EEG, reference groups were created at 0.5-year resolution by taking 133 overlapping bins covering the range 12-85.

EEG/ERP scores were transformed and validated for their normal distribution by using the same methodology in accordance with the predicate device: using four normality tests Anderson-Darling, the Cramer-von Mises, the Kolmogorov-Smirnov, and the Shapiro-Wilk tests. A score was considered to be normally distributed if at least 2 of the four tests were not statistically significant (p-value > 0.05) Normality of the EEG Scores was also tested using a Gaussian leave-one-out sensitivity test.

The normality test results are in accordance with the success rates presented in the predicate device statistical performance and, from a clinical perspective, allow for an accurate clinical interpretation of z-scores.

All Resting-EEG and ERP scores pass the 'two out of four' method tests (i.e., passing at least 2 out of 4 different normality tests) with a success rate above 97% and 98%, respectively, with Resting-EEG scores also passing the Gaussian leave-one-out sensitivity tests with a success rate larger than 97.5% an acceptable percentage of failures, given the large number of scores tested. These results are in accordance with the success rates presented in the predicate device statistical performance and allow for an accurate clinical interpretation of z-scores.

Poolability of the Reference Group data was tested with a linear regression model for each combination of ERP score or behavioral performance score and age-bin and checked for cases

with a significant age-effect ($p<0.05$) following False Discovery Rate (FDR) correction. All AOB and VGNG ERP scores pass the poolability test with a success rate of 99% and 100%, respectively. This is an acceptable percentage of failures, given the large amount of scores tested, allowing for a reliable division of the entire dataset into age groups.

The Bland-Altman analysis of the Test-Retest database provides test-retest reliability statistical estimates, for all combinations of tasks, conditions and parameters. These test-retest reliability results can be used by clinicians to estimate changes in BNA™ Scores between successive visits.

8. CONCLUSION

Based on the detailed comparison to the predicate devices, the performance testing, and the clinical testing, the BNA™ Platform can be found substantially equivalent to the predicate devices.