K121119

JUL 25 2014

510(k) SUMMARY

ElMindA Ltd.'s BNA™ Analysis System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: July 18, 2014

Proprietary Name of Device and Name/Address of Sponsor

BNA™ Analysis System

Common or Usual Name/ Classification Name

Electroencephalogram ("EEG")

Regulation Number

882.1400

Product Code

OLU

Predicate Devices

Neuroguide Analysis System (K041263)
Neuromarker Data Acquisition and Analysis Software (K050192)
Human Brain Index Software (K112077)

Intended Use / Indications for Use

The BNA™ Analysis System is to be used by qualified medical professionals for the post-hoc statistical analysis of the human electroencephalogram ("EEG"), utilizing evoked response potentials ("ERP"). This device is indicated for use in individuals 14 to 24 years of age. The BNA™ Analysis System is to be used with the auditory oddball task only.

Technological Characteristics / Principles of Operation

The BNA Analysis System is an accessory to EEG. The BNA Analysis System is a software device that is used to analyze EEG-ERP data with regards to conventional, well established characteristics of amplitude and latency. Statistical analysis is performed to express the differences between the patient

(individual) and a task-matched reference group in the indicated age group in the form of Z-scores.

The BNA Analysis System report displays the test results in the following format; (1) Test and Patient Information; (2) ERP waveforms; (3) Summarized patient results – Z-Score Tables, Z-Score Maps and BNA Composite Scores.

BNA Composite Scores are a calculation of the global comparison of the individual to the normative group (RBNM) for the following well-established EEG-ERP components: amplitude and absolute time. These calculations are a measure of the overall similarity of the single subject EEG-ERP components to the EEG-ERP components of the normative group (RBNM) based on Z-scores. The BNA scores should not be used as stand-alone information; rather, such scores should complement all of the information included in the report, as well as the clinical evaluation.

Performance Data

Clinical performance testing was conducted to assess the repeatability of the BNA scores between two identical test sessions that were conducted within 7(±3) days of each other. In order to assess the repeatability of the BNA scores, Bland-Altman analysis was performed. This analysis was performed for the three stimuli of the auditory oddball task and two BNA parameters (amplitude and absolute time) for each stimulus as shown in the table below.

Mean BNA Difference between Visits, Mean Standard Deviation (STD) of the Difference and Bland-Altman 95% Limits of Agreement by Stimulus and Parameter

Stimulus	Parameter	Mean Difference	STD of the Difference	Lower Bland-Altman 95% Limit of Agreement	Upper Bland-Altman 95% Limit of Agreement
Frequent	Amplitude	4.10	25.35	-45.60	53.79
	Absolute Time	3.02	23.56	-43.16	49.20
Novel	Amplitude	0.46	22.79	-44.20	45.13
	Absolute Time	5.44	27.19	-47.85	58.74
Target	Amplitude	-5.65	21.97	-48.71	37.41
	Absolute Time	-6.78	24.05	-53.91	40.36

The subject device software was developed, verified and validated according to the software development requirements as defined in the IEC 62304 and General Principles of Software Validation; Final Guidance for Industry and FDA Staff (FDA, CDRH, 11/1/02).

Substantial Equivalence

The BNA™ Analysis System is as safe and effective as the Neuroguide Analysis System (K041263), the Neuromarker Data Acquisition and Analysis Software (K050192), and the Human Brain Index Software (K112077). The BNA™ Analysis System has the same intended uses/indications for use, and similar technological characteristics and principles of operation as the identified

predicate devices (see table below). The minor technological differences between the BNA™ Analysis System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the BNA™ Analysis System is as safe and effective as the cleared predicate devices. Thus, the BNA™ Analysis System is substantially equivalent.

Comparison Table

BNA ANALYSIS SYSTEM SUBSTANTIAL EQUIVALENCE CHART				
	BNA™ Analysis System	**Human Brain Index Software (K112077)**	**Neuroguide Analysis System (K041263)**	**Neuromarker Data Acquisition and Analysis Software (K050192)**
Indications for Use	The BNA™ Analysis System is to be used by qualified medical professionals for the post-hoc statistical analysis of the human electroencephalogram ("EEG"), utilizing evoked response potentials ("ERP"). This device is indicated for use in individuals 14 to 24 years of age. The BNA™ Analysis System is to be used with the auditory oddball task only.	The HBIdb product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG), utilizing evoked response potentials (ERP). The HBIdb product is intended for use on children and adults from age 7 to 80 years.	For clinical use the NeuroGuide Analysis system is to be used by qualified medical or clinical professionals for the statistical evaluation of the human electroencephalogram (EEG).	The BRC software product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG), utilizing evoked response potentials (ERP).
Context of Use	To be used by qualified medical or clinical professionals. EEG data is collected at independent laboratory sites then transmitted to a Central Analysis Facility for processing against a database. Acquisition protocols and equipment utilized at each laboratory must meet required specifications to ensure uniformity of collected data.	To be used by qualified medical or clinical professionals. The EEG is recorded on a separate device under the standardized HBIdb conditions and is transferred to the HBIdb in EDF+ format for analysis.	To be used by qualified medical professionals. EEG data is collected at independent laboratory sites then transmitted to a Central Analysis Facility for processing against a database. Acquisition protocols and equipment utilized at each laboratory must meet required specifications to ensure uniformity of collected data.	To be used by qualified medical or clinical professionals. EEG data is collected at independent laboratory sites then transmitted to a Central Analysis Facility for processing against a database. Acquisition protocols and equipment utilized at each laboratory must meet required specifications to ensure uniformity of collected data.

	BNA™ Analysis System	Human Brain Index Software (K112077)	Neuroguide Analysis System (K041263)	Neuromarker Data Acquisition and Analysis Software (K050192)
Technology Characteristic				
Band Passing	Yes	Yes	Yes	Yes
Time-Frequency Analysis	Yes	Yes	Yes	Yes
Analysis of Individual Frequency Bands	Yes	Yes	Yes	Yes
Peak analysis	Yes	Yes	No	Yes
• Latency	Yes	Yes	No	Yes
• Amplitude	Yes	Yes	No	Yes
•				
Output Characteristic				
Topographical Maps	Yes	Yes	Yes	Yes
ERP Waveforms	Yes	Yes	No –	Yes
A result is provided that expresses the statistical difference between the single subject and the reference database in the form of a probability estimate	Yes	Yes	Yes	Yes
Comparison to Normative Database	Yes	Yes	Yes	Yes

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

July 25, 2014

ElMindA Ltd.
Dalia Dickman, PhD
VP Clinical & Regulatory Affairs
16 Haminhara Street
Beit Bachar
Herzliya 46586
Israel

Re: K121119
Trade/Device Name: BNA™ Analysis System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLU
Dated: September 3, 2013
Received: September 3, 2013

Dear Dr. Dickman:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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,

Carlos L. Pena -S

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)*
K121119

Device Name
BNA Analysis System

Indications for Use *(Describe)*
The BNA Analysis System is to be used by qualified medical professionals for the post-hoc statistical analysis of the human electroencephalogram ("EEG"), utilizing evoked response potentials ("ERP"). This device is indicated for use in individuals 14 to 24 years of age. The BNA Analysis System is to be used with the auditory oddball task only.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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:

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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."