



Food and Drug Administration
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November 17, 2014

BrainScope Company, Inc.
Michael Singer, Ph.D.
President and CEO
4350 East-West Highway
Suite 1050
Bethesda, MD 20814

Re: DEN140025
BrainScope Ahead 100, Models CV-100 and M-100
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.1450
Regulation Name: Brain Injury Adjunctive Interpretive Electroencephalograph
Assessment Aid
Regulatory Classification: Class II
Product Code: PIW
Dated: August 20, 2014
Received: August 20, 2014

Dear Dr. Singer:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the BrainScope Ahead 100, Models CV-100 and M-100, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

- The Ahead[®] 100, consisting of two models, i.e., the Ahead[®] M-100 and the Ahead[®] CV-100, is indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who are being considered for a head CT, but should not be used as a substitute for a CT scan. This device is to be used for this purpose in patients who sustained a closed head injury within 24 hours, clinically present as a mild traumatic brain injury with a Glasgow Coma Scale score (GCS) of 13-15, and are between the ages of 18-80 years.
- A negative BrainScope[®] Classification may correspond to brain electrical activity consistent with no structural brain injury visible on head CT in patients presenting as a mild traumatic brain injury, within 24 hours of injury.
- A positive BrainScope[®] Classification corresponds to brain electrical activity that may be present in both patients with or without a structural brain injury visible on head CT. A positive BrainScope[®] Classification does not establish the presence of a structural brain injury visible on head CT.

- The Ahead® 100 device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG (qEEG) parameters from frontal locations on a patient's forehead. The Ahead® 100 calculates and displays raw measures for the following standard qEEG measures: Absolute and Relative Power, Asymmetry, Coherence and Fractal Dimension. These raw measures are intended to be used for post hoc analysis of EEG signals for interpretation by a qualified user.
- The Ahead® M-100 model additionally stores and displays an electronic version of the Military Acute Concussion Evaluation (MACE) cognitive assessment and user-entered responses to the MACE questions. There is no interaction between EEG-related functionality, including analyzing and displaying brain electrical activity, and the function of storing and displaying MACE information.
- The Ahead® 100 is intended for use by physicians, or under the direction of a physician, who have been trained in the use of the device.
- The Ahead® 100 is a prescription use device.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the BrainScope Ahead 100, Models CV-100 and M-100, and substantially equivalent devices of this generic type, into class II under the generic name, Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid.

FDA identifies this generic type of device as:

Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid. A Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the structural condition of the patient's brain in the setting of trauma. A Brain Injury Adjunctive Interpretive EEG Assessment Aid is for use as an adjunct to standard clinical practice only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On August 20, 2014, FDA received your *de novo* requesting classification of the BrainScope Ahead 100, Models CV-100 and M-100 into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the BrainScope Ahead 100, Models CV-100 and M-100 into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the BrainScope Ahead 100, Models CV-100 and M-100 indicated for the following:

- The Ahead[®] 100, consisting of two models, i.e., the Ahead[®] M-100 and the Ahead[®] CV-100, is indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who are being considered for a head CT, but should not be used as a substitute for a CT scan. This device is to be used for this purpose in patients who sustained a closed head injury within 24 hours, clinically present as a mild traumatic brain injury with a Glasgow Coma Scale score (GCS) of 13-15, and are between the ages of 18-80 years.
- A negative BrainScope[®] Classification may correspond to brain electrical activity consistent with no structural brain injury visible on head CT in patients presenting as a mild traumatic brain injury, within 24 hours of injury.
- A positive BrainScope[®] Classification corresponds to brain electrical activity that may be present in both patients with or without a structural brain injury visible on head CT. A positive BrainScope[®] Classification does not establish the presence of a structural brain injury visible on head CT.
- The Ahead[®] 100 device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG (qEEG) parameters from frontal locations on a patient's forehead. The Ahead[®] 100 calculates and displays raw measures for the following standard qEEG measures: Absolute and Relative Power, Asymmetry, Coherence and Fractal Dimension. These raw measures are intended to be used for post hoc analysis of EEG signals for interpretation by a qualified user.
- The Ahead[®] M-100 model additionally stores and displays an electronic version of the Military Acute Concussion Evaluation (MACE) cognitive assessment and user-entered responses to the MACE questions. There is no interaction between EEG-related functionality, including analyzing and displaying brain electrical activity, and the function of storing and displaying MACE information.
- The Ahead[®] 100 is intended for use by physicians, or under the direction of a physician, who have been trained in the use of the device.
- The Ahead[®] 100 is a prescription use device.

can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device

type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Adverse Tissue Reaction	Biocompatibility Labeling
Equipment Malfunction Leading to Injury to User/Patient (shock, burn, or mechanical failure)	Electrical safety, thermal, and mechanical testing Electromagnetic Compatibility Testing Labeling
Delay in Treatment or Unnecessary Treatment due to Hardware or Software Failure	Performance testing Hardware and Software verification, validation and hazard analysis Electromagnetic Compatibility Testing Technical Parameters Labeling
False Result due to Incorrect Artifact Reduction	Software verification and validation Labeling
False Result due to Incorrect Placement of Electrodes	Clinical performance testing Labeling
False Result when a Brain Injury Adjunctive Interpretive EEG Assessment Aid Impacts the Clinical Decision	Clinical performance testing Device design characteristics Labeling
Use Error	Clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid is subject to the following special controls:

1. The technical parameters of the device, hardware and software, must be fully characterized and include the following information:
 - a. Hardware specifications must be provided. Appropriate verification, validation and hazard analysis must be performed.
 - b. Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's condition, must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.
2. The device parts that contact the patient must be demonstrated to be biocompatible.
3. The device must be designed and tested for electrical safety, electromagnetic compatibility (EMC), thermal and mechanical safety.

4. Clinical performance testing must demonstrate the accuracy, precision – repeatability and reproducibility, of determining the EEG-based interpretation, including any specified equivocal zones (cut-offs).
5. Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for the medical condition for which the device is indicated. Performance measures must demonstrate device performance characteristics per the intended use in the intended use environment. Performance measurements must include sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) with respect to the study prevalence per the device intended use.
6. The device design must include safeguards to ensure appropriate clinical interpretation of the device output (e.g., use in appropriate patient population, or for appropriate clinical decision).
7. The labeling and training information must include:
 - a. A warning that the device is not to be used as a stand-alone diagnostic.
 - b. A detailed summary of the clinical performance testing, including any adverse events and complications.
 - c. The intended use population and the intended use environment.
 - d. Any instructions technicians should convey to patients regarding the collection of EEG data.
 - e. Information allowing clinicians to gauge clinical risk associated with integrating the EEG interpretive assessment aid into their diagnostic pathway.
 - f. Information allowing clinicians to understand how to integrate the device output into their diagnostic pathway when the device is unable to provide a classification or final result.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Jay Gupta at 301-796-2795.

Sincerely yours,

Jonette R. Foy -S

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Deputy Director
for Engineering and Science Review
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