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September 22, 2016

Brainscope Company Inc
Michael Singer, PhD
CEO
4350 East West Highway
Suite 1050
Bethesda, Maryland 20814

Re: K161068
Trade/Device Name: Ahead 300
Regulation Number: 21 CFR 882.1450
Regulation Name: Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid
Regulatory Class: Class II
Product Code: PIW, PKQ, OLU
Dated: August 24, 2016
Received: August 24, 2016

Dear Dr. Singer:

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 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>. 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 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,

Michael J. Hoffmann -A

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

Indications for Use

510(k) Number (if known)

K161068

Device Name

Ahead® 300

Indications for Use (Describe)

- The Ahead 300 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, who sustained a closed head injury within 72 hours, present with a Glasgow Coma Scale score (GCS) of 13-15, and are between the ages of 18-85 years. The Ahead 300 should not be used as a substitute for a CT scan.
- The Ahead 300 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 300 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.
- A negative Ahead 300 Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, likely corresponds to those with no structural brain injury visible on head CT.
- A positive Ahead 300 Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, likely corresponds to those with a structural brain injury visible on head CT.
- An equivocal Ahead 300 Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.
- The Ahead 300 provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram(EEG).
- The Ahead 300 also provides clinicians with quantitative measures of cognitive performance to aid in the assessment of an individual's level of cognitive function. These measures do not interact with any other device measures, and are stand alone.
- The Ahead 300 also stores and displays electronic versions of standardized clinical assessment tools that should be used in accordance with the assessment tools' general instructions. These tools do not interact with any other device measures, and are stand alone.

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)

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510(k) SUMMARY¹

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Date Prepared: September 20, 2016

Device Proprietary Name: Ahead® 300

Device Common Name: Brain Injury Adjunctive Interpretive
Electroencephalograph Assessment Aid

Device Classification Name: Brain Injury Adjunctive Interpretive
Electroencephalograph Assessment Aid

Classification Regulation: 21 CFR § 882.1450

Panel: Neurology

Product Codes: PIW, PKQ, OLU

Predicate Devices: BrainScope Ahead 200 (K143643)
ANAM Test System: Military Battery (K150154)
Neurometric Analysis System (K974748)

¹ Prepared in accordance with 21 CFR § 807.87(h) and 21 CFR § 807.92(c).
Ahead® 300 510(k) Summary



Device Description:

The Ahead 300 is a portable, non-invasive, non-radiation emitting, point of care device intended to provide results and measures to support clinical assessments and aid in the diagnosis of traumatic brain injury (TBI).

The Ahead 300 is a product of the continual technological evolution of the BrainScope Ahead 200 device. The device platform is essentially identical, and the core capability of the Ahead 300 remains the same as the Ahead 200. Both devices provide an algorithm-based structural injury classification of head injured patients using EEG features. The Ahead 300's accuracy is improved over the Ahead 200. The Ahead 300 also incorporates functions performed by additional legally marketed predicate devices, including an overall assessment of functional brain injury utilizing EEG, and two well-accepted cognitive performance tests.

Indications for Use:²

The Ahead 300's Indications for Use reflect the improved performance of the Ahead 300 as compared to the primary predicate, the Ahead 200. The Indications for Use also provide additional information to medical professionals and practitioners upon which they can make more informed decisions about the clinical diagnosis of patients that have sustained a closed head injury, by incorporating relevant portions of the Indications for Use associated with each legally marketed secondary predicate, thereby improving the overall benefit/risk ratio compared to the predicate devices. As such, the Ahead 300 and the predicate devices are not identical, but the combined set of Indications for Use support the Intended Use of the Ahead 300. The Ahead 300's Indications for Use are as follows:

- The Ahead 300 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, who sustained a closed head injury within 72 hours, present with a Glasgow Coma Scale score (GCS) of 13-15, and are between the ages of 18-85 years. The Ahead 300 should not be used as a substitute for a CT scan.
- The Ahead 300 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 300 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.

² The Ahead 300 is a combination device encompassing indications for use for 3 predicate devices. The Indications for Use statement for the Ahead 300 is a composite of the indications associated with the predicates. The differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicates. The subject and predicate devices have the same overall intended use.

- A negative Ahead 300 Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, likely corresponds to those with no structural brain injury visible on head CT.
- A positive Ahead 300 Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, likely corresponds to those with a structural brain injury visible on head CT.
- An equivocal Ahead 300 Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.
- The Ahead 300 provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG).
- The Ahead 300 also provides clinicians with quantitative measures of cognitive performance to aid in the assessment of an individual's level of cognitive function. These measures do not interact with any other device measures, and are stand alone.
- The Ahead 300 also stores and displays electronic versions of standardized clinical assessment tools that should be used in accordance with the assessment tools' general instructions. These tools do not interact with any other device measures, and are stand alone.

Table 1: Indications for Use Comparison to Predicate devices

Proposed Device: Ahead 300	Primary Predicate: Ahead 200	Secondary Predicate: ANAM Test System – Military Battery	Secondary Predicate: Neurometric Analysis System	Comments
<p>The Ahead 300 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, sustained a closed head injury within 72 hours, present with a Glasgow Coma Scale score (GCS) of 13-15, and are between the ages of 18-85 years. The Ahead 300 should not be used as a substitute for a CT scan.</p>	<p>The Ahead 200, consisting of two models, i.e., the Ahead M-200 and the Ahead CV-200, 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.</p>	<p>N/A</p>	<p>N/A</p>	<p>Equivalent to primary predicate, with modifications reflecting the Ahead 300 clinical trial results, including:</p> <ul style="list-style-type: none"> • an expanded injury time window (72 hours versus 24 hours for the Ahead 200), • an expanded patient age range (18-85 years versus 18-80 years for the Ahead 200).
<p>The Ahead 300 device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG</p>	<p>The Ahead 200 device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard</p>	<p>N/A</p>	<p>N/A</p>	<p>Same as primary predicate.</p>

Proposed Device: Ahead 300	Primary Predicate: Ahead 200	Secondary Predicate: ANAM Test System – Military Battery	Secondary Predicate: Neurometric Analysis System	Comments
<p>(QEEG) parameters from frontal locations on a patient’s forehead. The Ahead 300 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.</p>	<p>quantitative EEG (QEEG) parameters from frontal locations on a patient’s forehead. The Ahead 200 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.</p>			
<p>A negative Ahead 300 Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, likely corresponds to those with no structural brain injury visible on head CT.</p>	<p>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.</p>	N/A	N/A	<p>Equivalent to primary predicate, with proposed changes in the Ahead 300 language reflecting the significantly improved accuracy demonstrated by the Ahead 300 trial results.</p>
<p>A positive Ahead 300 Structural Injury Classification using brain</p>	<p>A positive BrainScope Classification corresponds to</p>	N/A	N/A	<p>Equivalent to primary predicate, with proposed changes in the Ahead 300</p>

Proposed Device: Ahead 300	Primary Predicate: Ahead 200	Secondary Predicate: ANAM Test System – Military Battery	Secondary Predicate: Neurometric Analysis System	Comments
electrical activity in patients who sustained a closed head injury within 72 hours, likely corresponds to those with a structural brain injury visible on head CT.	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.			language reflecting the improved accuracy demonstrated by the Ahead 300. In addition, the statement regarding false positives in the IFU of the predicate is now expanded and moved to the Safety Summary section of the User Manual.
An equivocal Ahead 300 Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.	N/A	N/A	N/A	The Ahead 200 has no equivocal zone. This zone has been added to provide additional clinical information to the clinician for use in the diagnostic process, providing information about patients who are close to the binary threshold for classification.
The Ahead 300 provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG).	N/A	N/A	The Neurometric Analysis system is to be used by qualified medical professionals for the post—hoc statistical evaluation of the human electroencephalogram (EEG).	The Ahead 300 and NAS both use multivariate composite features as a measure of abnormality of overall brain function relative to age expected normal values, and the functionality is consistent with the intended use of

Proposed Device: Ahead 300	Primary Predicate: Ahead 200	Secondary Predicate: ANAM Test System – Military Battery	Secondary Predicate: Neurometric Analysis System	Comments
				analyzing a patient’s electroencephalograph (EEG) to provide an interpretation of the patient’s neuropsychiatric condition, as well as to record, measure, and display brain electrical activity. Removal of “post-hoc” analysis reflects the advances in technology allowing for real-time analysis on the device, but does not change functionality.
The Ahead 300 also provides clinicians with quantitative measures of cognitive performance to aid in the assessment of an individual’s level of cognitive functioning. These measures do not interact with any other device measures, and are stand alone.	N/A	The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual’s level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for	N/A	Equivalent to secondary predicate.

Proposed Device: Ahead 300	Primary Predicate: Ahead 200	Secondary Predicate: ANAM Test System – Military Battery	Secondary Predicate: Neurometric Analysis System	Comments
		evaluating cognitive function.		
<p>The Ahead 300 also stores and displays electronic versions of standardized clinical assessment tools that should be used in accordance with the assessment tools' general instructions. These tools do not interact with any other device measures, and are stand alone.</p>	<p>The Ahead M-200 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.</p>	N/A	N/A	<p>Equivalent to primary predicate. IFU language is generalized to reflect the fact that the Ahead 300 stores and displays multiple assessment tools as part of its library function. Users will know the full capability of the Ahead 300 from the User Manual.</p>

Comparison of Technological Characteristics with the Predicate Devices:

While there are differences in technological characteristics when comparing the Ahead 300 with the predicate devices, the differences do not raise different questions of safety and effectiveness.

The core capability of the Ahead 300 remains the same as the Ahead 200. The device hardware and electrode headset are essentially identical. The device software (including algorithms) is based on the same fundamental architecture/platform with expanded scope to incorporate additional functionalities.

The technological characteristics associated with the additional capability to perform two well-accepted standard Cognitive Performance tests are equivalent to the ANAM Test System: Military Battery, and the technological characteristics associated with the Brain Function Index are equivalent to those of the Neurometric Analysis System.

Table 2, Technological Comparison to Predicate Devices

Topic / Area	Proposed Device: Ahead 300	Primary Predicate: Ahead 200	Secondary Predicate: ANAM Test System: Military Battery	Secondary Predicate: Neurometric Analysis System
Platform	Trimble T41 mobile device, Android OS	Trimble T41 mobile device, Android OS	PC: Dell Latitude E6440 Laptop Computer, two button USB connected mouse, and Windows 7 Operating System	Stand-alone post hoc analysis software that may be run on IBM-compatible computer systems.
Processed EEG Bandwidth	1kHz sampled data with DC to 300Hz bandwidth and 100Hz sampled data with 0.67Hz to 43Hz bandwidth	1kHz sampled data with DC to 300Hz bandwidth and 100Hz sampled data with 0.3Hz to 43Hz bandwidth	N/A	N/A
Common Mode Rejection Ratio (CMRR)	< -100 dB (or better)	< -100 dB (or better)	N/A	N/A
System Noise Floor	< 0.4 μ V in 0.67 Hz to 43Hz bandwidth	< 0.4 μ V in 0.3 Hz to 43Hz bandwidth	N/A	N/A
ADC Resolution	45 nV/bit	45 nV/bit	N/A	N/A
ADC Sampling Rate	1000 Hz, down sampled to 100 Hz for algorithm processing	1000 Hz, down sampled to 100 Hz for algorithm processing	N/A	N/A
Wireless data	No wireless communication	No wireless communication	N/A	N/A

Topic / Area	Proposed Device: Ahead 300	Primary Predicate: Ahead 200	Secondary Predicate: ANAM Test System: Military Battery	Secondary Predicate: Neurometric Analysis System
transmission	capability.	capability		
Electrode Placement System	The International 10-20 System	The International 10-20 System	N/A	N/A
Electrode Positions Utilized	Fp1, Fp2, Fpz, AFz, F7, F8, A1, A2	Fp1, Fp2, Fpz, AFz, F7, F8, A1, A2	N/A	N/A
Electrode Material	Single use Ag/AgCl electrode sensor array headset with solid gel	Single use Ag/AgCl electrode sensor array headset with solid gel	N/A	N/A
Real Time EEG Display	Yes	Yes	N/A	N/A
Classification Algorithm (Structural Injury Classification)	Three tier classification with results of Negative, Equivocal and Positive outputs.	Two tier classification classifier with results of Positive or Negative outputs.	N/A	N/A
Results Presentation and Reporting Features	Specific raw measures. EEG playback. Structural injury classification and brain function index display. Cognitive performance raw and standard scores including percentiles. Electronic versions of Standard Clinical Assessments.	Specific raw measures. EEG playback. Structural injury classification Electronic version of the Military Acute Concussion Evaluation (MACE) results.	Provides raw scores, standard scores and percentiles (calculated with normative database) for each test. Also yields the ANAM Composite Scores (ACS) summarizing performance across the test battery.	Output includes z-scores, standard deviations and multivariate combinations of z-scores and "hits" presented in tabular format.

Non-Clinical Performance Data:

The following non-clinical tests were performed to support the determination of substantial equivalence:

- Bench testing including device software (including algorithms), hardware (including disposable electrode headset), and systems.
- In addition, testing was performed as per the following performance standards:

- IEC 60601-1/A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2/A1;2007 Medical electrical equipment - Section 1.2 Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-6/A1:2013 General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- IEC 60601-2-26:2012 Particular requirements for the basic safety and essential performance of electroencephalographs
- ANSI/AAMI EC12:2000/(R)2010 Disposable ECG Electrodes
- ANSI/AAMI/ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ANSI/AAMI/ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ANSI/AAMI/ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization
- MIL-STD-810G, Department of Defense Test Method Standard for Environmental Engineering Considerations and Laboratory Tests
- IEC 60529 (2004) Degree of Protection Provided by Enclosures
- ASTM D4169 – 09, Standard Practice for Performance Testing of Shipping Containers and Systems

The results of the non-clinical (bench) testing demonstrate that the Ahead 300 meets or exceeds the performance of the predicate devices. The technological differences between the Ahead 300 and the predicates do not raise different questions of safety or effectiveness.

Clinical Performance Data:

The target population of the B-AHEAD III validation trial was aligned with that of the B-AHEAD II validation trial for the predicate device Ahead 200, and consisted of 720 adults; 60.7% males, mean age of 43.12 years, mean GCS of 14.97 and an average time since injury of 13.9 hours.

The co-primary endpoints, as defined by sensitivity and specificity of the study device classification distinguishing CT+ from CT-, successfully exceeded the performance goals, and demonstrated significantly improved performance over Ahead 200. A high negative predictive value (NPV), and repeatability and reproducibility of the device result were also successfully demonstrated.

The secondary endpoints reflect the evolution of the Ahead system, providing additional quantitative information about brain function using the EEG Brain Function Index which



scales with severity of functional impairment, and reducing the risk of false negatives through the addition of the Equivocal Zone for classification of structural TBI. The Ahead 300 validation trial achieved secondary endpoints related to these two functionalities.

The Ahead 300 clinical validation trial successfully achieved its target performance, and demonstrating enhanced performance compared to the Ahead 200.

Conclusion:

The Ahead 300 is a product of the continual technological evolution of the previously FDA cleared Ahead 200 device. The Ahead 300 is a “combination device” that incorporates additional capabilities associated with the legally marketed ANAM Test System: Military Battery and the Neurometric Analysis System.

The Ahead 300 has the same intended use as the Ahead 200, the ANAM Test System: Military Battery, and the Neurometric Analysis System. The Ahead 300’s Indications for Use statement has been modified to incorporate the relevant portions of the indications associated with each legally marketed predicate device and the slight differences do not alter the device’s intended use, nor do they affect the safety and effectiveness of the device relative to the predicates.

The technological characteristics of the Ahead 300 are very similar to the previously FDA cleared Ahead 200, with the additional information generating capabilities of the legally marketed ANAM Test System: Military Battery and the Neurometric Analysis System.

The technological characteristics of the Ahead 300 when compared to the predicate devices do not raise new questions of safety or effectiveness, and sufficient non-clinical performance data and clinical performance data has been provided to demonstrate that the Ahead 300 is as safe and effective as the predicate devices.

The Ahead 300 is substantially equivalent to the Ahead 200, and the legally marketed ANAM Test System: Military Battery and the Neurometric Analysis System.