DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 15, 2015

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

Re: K143643
Trade/Device Name: BrainScope Ahead 200 (models M-200 and CV-200)
Regulation Number: 21 CFR 882.1450
Regulation Name: Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid
Regulatory Class: Class II
Product Code: PIW
Dated: April 15, 2015
Received: April 15, 2015

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" (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,

Felipe Aguel -S

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

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)*
K143643

Device Name
BrainScope Ahead 200 (models M-200 and CV-200)

Indications for Use *(Describe)*

• 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.

• 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® 200 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® 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.

• 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.

• The Ahead® 200 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® 200 is a prescription use device.

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.

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Premarket Notification 510(k) Summary
[Ahead® 200]

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter's Name and Address:	BrainScope Company, Inc. 4350 East West Highway Suite #1050 Bethesda, Maryland 20814 Telephone Number: (240) 752-7680 Fax Number: (240) 752-7679
Company Contact Person Phone: Fax: Email:	Michael E. Singer, Ph.D., President and CEO (240) 752-7680 (240) 752-7679 michael.singer@brainscope.com
Submission Correspondent Phone: Fax: Email:	Michael E. Singer, Ph.D., President and CEO (240) 752-7680 (240) 752-7679 michael.singer@brainscope.com
Device Name	BrainScope® Ahead® 200 (Models M-200 and CV-200)
Regulation Name	Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid
Regulation Number	21 CFR 882.1450
Classification	Class II
Product Code	PIW
Predicate Device	BrainScope® Ahead® 100 (Models M-100 and CV-100) (DEN 140025)
Date of Submission	December 22, 2014

1. Description of the Device

The BrainScope® Ahead® 200 is a Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid, Class II device. It is a portable, non-sterile, non-invasive, non-radiation emitting, point of care, electroencephalogram (EEG) device and is intended to provide an objective assessment of brain electrical activity associated with traumatic brain injury (TBI). This 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.

The BrainScope® Ahead® 200 is comprised of two hardware components: the Handheld Device and the disposable Electrode Headset with patient application supplies. The main software components of the Ahead 200 are the application software and the BrainScope Algorithm Library (BSAL). The Ahead® 200 has two models: (1) the Ahead® M-200, which is intended for use by the military, and (2) the Ahead® CV-200, which is intended for civilian use. The Ahead® M-200 and the Ahead® CV-200 have the same indications for use and intended uses with the exception that the Ahead® M-200 model additionally stores and displays an electronic version of the Military Acute Concussion Evaluation (MACE) 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® M-200 and the Ahead® CV-200 have identical technological characteristics except that the Ahead® M-200 contains the additional MACE feature, i.e., an electronic version of the paper and pencil based MACE.

The Ahead® 200 has the following similarities to the cleared predicate device:

- Same intended use
- Same operating principle
- Same fundamental scientific technology
- Same algorithm software

2. Intended Use of the Device

- The Ahead® 200, with models M-200 and 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.
- 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® 200 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® 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.
- 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.
- The Ahead® 200 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® 200 is a prescription use device.

3. Summary of Performance Data and Substantial Equivalence

The Ahead® 200, models M-200 and CV-200, was designed and verified in accordance with the risk analysis and product requirements. All tests were conducted on the new model to establish substantial equivalence to the predicate (Ahead® 100, models M-100 and CV-100, DEN 140025). The Ahead® 200, models M-200 and CV-200, was tested and shown to be compliant with the following standards:

1. ANSI/AAMI ES60601-1:2005/(R)2012 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
2. CAN/CSA C22.2 No 601.1-08(R2013), "Medical Electrical Equipment, Part 1: General Requirements for Safety"
3. IEC/EN 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (including PEMS clause 14)
4. IEC 60601-2-26:2012 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
5. IEC/EN 60601-1-2:2007 Medical electrical equipment - Section1.2 Collateral standard: Electromagnetic compatibility - Requirements and tests
6. ISO 10993-1:2009 - Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process
7. ANSI/AAMI EC12:2000 – Disposable ECG Electrodes

The following testing was conducted to demonstrate the safety and efficacy of the Ahead® 200, Models M-200 and CV-200, in its intended environment.

Table 1.0 – Design Verification Test

Design Verification Test	Result
Software (including User Interface) Verification Testing	Pass
Hardware Verification	Pass
System Performance and Functionality	Pass
Algorithm Performance	Pass
Packaging Testing	Pass
Basic Safety and Essential Performance (IEC 60601-1, 3rd ed.) including PEMS clause 14 for Software	Pass
Electromagnetic Compatibility	Pass
Biocompatibility	Pass
Reliability	Pass

This 510(k) submission represents the results of the testing and the detailed description to demonstrate that the Ahead® 200, models M-200 and CV-200, is substantially equivalent to the Ahead® 100, models M-100 and CV-100 (DEN 140025).

The table 2.0 below provides a design comparison of the Ahead® 200 to the predicate Ahead® 100 (DEN 140025)

Table 2.0 Comparison between Ahead® 200 & the predicate device Ahead® 100

	Ahead® 200, models M-200 and CV-200	**Ahead® 100, models M-100 and CV-200 (Predicate Device, DEN100425)**	**Notes**
Major System Components	1. Handheld computer and DAB 2. Disposable Electrode Headset 3. Software 4. Algorithm 5. Accessories	1. Handheld Unit including patient interface cable 2. Disposable Electrode Headset 3. Software 4. Algorithm 5. Accessories	Same
Components Physical Dimension			
Device Size (mm)	Handheld Unit: 90x165x30 Data Acquisition Board (DAB): 130x110x50	114x200x51	Ahead® 200 handheld is smaller and DAB is ergonomic
Weight	Max 0.620kg (1.4 lbs.)	Max 1.4kg (2.5lbs)	Ahead® 200 is lighter
Ingress Protection and Operational Environment			
Ingress Protection	IP54 minimum as per IEC 60529	IP4X as per IEC 60529	Ahead® 200 is much better protected from solid and liquid ingress
Operational Temperature	0°C to 38°C (32°F to 100°F)	0°C to 50°C (32°F to 122°F)	Ahead 100 has wider range but both devices meet product requirements
Electrical Hardware			

	Ahead® 200, models M-200 and CV-200	**Ahead® 100, models M-100 and CV-200 (Predicate Device, DEN100425)**	**Notes**
Location of Analog to Digital Conversion (ADC)	Immediately after Electrode Headset	After patient interface cable	Ahead® 200 signal chain is more immune to noise
Common Mode Rejection Ratio (CMRR)	< -100 dB	< - 85 dB	Ahead® 200 better CMRR
Low pass filtering prior to signal processing	0.3 Hz to 43Hz	0.3 Hz to 43Hz	Same
System Noise Floor	< 0.4 µV in 0.3 Hz to 43Hz bandwidth	< 0.4 µV in 0.3 Hz to 43Hz bandwidth	Same
ADC Resolution	45 nV/bit	31.2nV/bit	Both devices have better resolution than their noise floor
ADC Sampling Rate	1000 Hz, down sampled to 100 Hz for algorithm processing	1000 Hz, down sampled to 100 Hz for algorithm processing	Processing bandwidth used by algorithm is same
Data Channel	7	7	same
Storage Capacity			
Total Capacity	32 GB in micro-SD card	4 GB in CF card	Ahead® 200 has significantly more storage memory space
Battery			
Battery Chemistry	Li-ion rechargeable battery pack	Li-ion rechargeable battery pack	Same
Battery Run-Time	Minimum of 10 patient recordings sessions in one charge. Equivalent of 120 minutes of effective operation.	Minimum of 140 minutes of effective operation.	Ahead® 100 is better in raw numbers but both devices meet requirement.
Battery Longevity	1-2 years of service before replacement.	1-2 years of service before replacement.	Same

	Ahead® 200, models M-200 and CV-200	**Ahead® 100, models M-100 and CV-200 (Predicate Device, DEN100425)**	**Notes**
Battery Safety Considerations	IEC 60950-1:2005 compliant. Evaluated as part of IEC 60601-1 certification	The battery pack is equipped with a thermal protection device to prevent excess charge and discharge currents. Battery and battery pack safety evaluated as part of IEC 60601-1 certification.	Verification methodology was different as data on Ahead® 100 battery pack was limited. Ahead® 200 battery is fully certified and did not require additional testing.
Battery Charging	Full recharge in less than 4 hours in device turned off mode	Full recharge in less than 3.5 hours in device turned off mode	Ahead® 200 battery takes 30 minutes more to charge.
Accessories	Battery charger and charging cable	Battery charger and charging cable	Actual battery charger and cables are different as the interface connectors and battery packs are different. Accessories for both devices are fully compliant to IEC 60601-1.
Electrode Headset			
Electrode Placement System	The International 10-20 System is used as a basis for electrode placement.	The International 10-20 System is used as a basis for electrode placement.	Same
Electrode Positions Utilized	Fp1, Fp2, Fpz, AFz, F7, F8, A1, A2	Fp1, Fp2, Fpz, AFz, F7, F8, A1, A2	Same

	Ahead® 200, models M-200 and CV-200	**Ahead® 100, models M-100 and CV-200 (Predicate Device, DEN100425)**	**Notes**
Electrode Material	Single use Ag/AgCl electrode sensor array headset with solid gel	Single use Ag/AgCl electrode sensor array headset with wet gel	Difference in the electrolytic gel material. Despite difference both electrodes meet ANSI/AAMI EC12 standard for electrode electrical performance.
Electrode Impedance Test	Yes, at start of recording and during recording	Yes, at start of recording	Ahead® 200 provides better usability and data quality by performing continuous out of (EEG) band impedance measurement.
Headset Authentication	Yes. Ahead 200 utilizes hardware based headset authentication.	No such authentication is possible on the Ahead 100.	Ahead® 200 provides better usability and data quality by ensuring use of approved headsets.
System Software and Algorithms			
Operating System	Android	MontaVista Linux	Ahead® 200 utilizes a modern and updated mobile OS compared to the Ahead 100.

	Ahead® 200, models M-200 and CV-200	**Ahead® 100, models M-100 and CV-200 (Predicate Device, DEN100425)**	**Notes**
Graphical User Interface – Screens	Patient Information Electrode Impedance Raw EEG Waveform Dashboard Screen GCS score and warning IFU warnings Classification Results Data Review screen MACE (military version)	Patient Information Electrode Impedance Raw EEG Waveform GCS score and warning IFU warnings Classification Results Data Review screen MACE (military version)	Ahead® 200 improves usability by including the Dashboard screen. The Dashboard screen gives the user real-time indication of the progress of on-going EEG recording.
Encryption	AES-128 for intra-device communication	None for intra-device communication	Ahead® 200 has enhanced encryption
Automatic Artifacting	8 types of artifact detection	8 types of artifact detection	Same
Classification Algorithm	Harmony	Harmony	Same
Real Time EEG Display	Yes	Yes	Same
Data Analysis	• Conversion from time domain to frequency domain • Derivation of multiple features such as absolute power, relative power, coherence, etc. • Calculation of a discriminant function for structural injury	• Conversion from time domain to frequency domain • Derivation of multiple features such as absolute power, relative power, coherence, etc. • Calculation of a discriminant function for structural injury	Same

	Ahead® 200, models M-200 and CV-200	Ahead® 100, models M-100 and CV-200 (Predicate Device, DEN100425)	Notes
Results Presentation	• Positive and Negative BrainScope classification as described in IFU • Display screens with information on specific raw measures • EEG playback • The Ahead® M-200 model additionally stores and displays an electronic version of the Military Acute Concussion Evaluation (MACE) cognitive assessment	• Positive and Negative BrainScope classification as described in IFU • Display screens with information on specific raw measures • EEG playback • The Ahead® M-100 model additionally stores and displays an electronic version of the Military Acute Concussion Evaluation (MACE) cognitive assessment	Same
Compliance to Standards			
ISO 14971: 2000 Risk Management	Yes	Yes	Same
ISO 10993-1:2009 - Biological evaluation of medical devices	Yes	Yes	Same
ANSI/AAMI EC12:2000	Yes	Yes	Same
IEC60601-1 - General requirements for basic safety and essential performance	Yes, for 3rd edition	Yes, for 2nd edition	Ahead® devices were compliant to recognized consensus versions at the time of submission

	Ahead® 200, models M-200 and CV-200	Ahead® 100, models M-100 and CV-200 (Predicate Device, DEN100425)	Notes
IEC 60601-1-2:2007 Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	Yes	Yes	Same
IEC 60601-2-26: Particular Requirements for the Safety of Electro-encephalographs	Yes, compliant with 2012 version	Yes, compliant with 2002 version (for use with 2nd ed.)	Ahead® 200 compliant with updated version of standard
ASTM D4169-09, performance of packaging	Yes, compliant to DC 13, AL 1	Yes, compliant to DC 13, AL 2	Ahead® 200 compliant to stricter limits on same tests.

The table 3.0 below provides a comparison summary of the features of Ahead® 200 to the predicate device, the Ahead® 100.

Table 3.0 Comparison Summary of Features

Functional Features	Same/Different
Indications	Same
Technology	Same fundamental technology with current faster operating system
Software Algorithm	Same Harmony algorithm

Functional Features	Same/Different
User Interface	Same features but Ahead® 200 has improved usability by including the Dashboard screen. The Dashboard screen gives the user real-time indication of the progress of on-going EEG recording.

4. Conclusion

The information and data provided in this 510(k) notification establishes that the Ahead® 200, with models M-200 and CV-200, is substantially equivalent to the currently cleared device Ahead® 100, models M-100 and CV-100. The intended use is identical to the predicate device. The proposed device Ahead® 200 shares the basic design and fundamental operating principles to the currently cleared device (Ahead® 100, DEN 140025).