September 11, 2019

BrainScope Company, Inc.
Michael Singer
CEO
4330 East West Highway, Suite #1000
Bethesda, Maryland 20814

Re: K190815
Trade/Device Name: BrainScope TBI
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: July 19, 2019
Received: July 22, 2019

Dear Michael 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. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190815

Device Name
BrainScope TBI (model: Ahead 500)

Indications for Use *(Describe)*

• BrainScope TBI is a multi-modal, multi-parameter assessment indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury, and have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion/mild traumatic brain injury (mTBI)).

• BrainScope TBI provides a multi-parameter measure (Concussion Index (CI)) to aid in the evaluation of concussion in patients between the ages of 13–25 years who present with a GCS score of 15 following a head injury within the past 72 hours (3 days), in conjunction with a standard neurological assessment of concussion. The CI is computed from a multivariate algorithm based on the patient's electroencephalogram (EEG), augmented by neurocognitive measures and selected clinical symptoms.

• The BrainScope TBI Structural Injury Classification ("SIC") uses brain electrical activity (EEG) to determine the likelihood of structural brain injury visible on head CT for patients between the ages of 18-85 years (have a GCS score of 13 – 15), have sustained a closed head injury within the past 72 hours (3 days) who are being considered for a head CT. BrainScope TBI should not be used as a substitute for a CT scan. Negative likely corresponds to those with no structural brain injury visible on head CT. Positive likely corresponds to those with a structural brain injury visible on head CT. Equivocal may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.

• BrainScope TBI provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG), aiding in the evaluation of head injury as part of a multi-modal, multi-parameter assessment, in patients 18-85 years of age (have a GCS score of 13 – 15) who have sustained a closed head injury within the past 72 hours (3 days).

• The BrainScope TBI 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 BrainScope TBI 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.

• BrainScope TBI also provides clinicians with quantitative measures of cognitive performance in patients 13-85 years of age to aid in the assessment of an individual's level of cognitive function. These measures interact with the CI and can be used stand alone.

• BrainScope TBI 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY[1]

Submitter:	BrainScope® Company, Inc. 4330 East West Highway Suite #1000 Bethesda, MD 20814 Phone: (240) 752-7680 Fax: (240) 752-7679 www.brainscope.com
Contact:	Michael E. Singer, Ph.D. Executive Chairman BrainScope Company, Inc. Phone: (240) 752-7677 Fax: (240) 752-7679 Email: michael.singer@brainscope.com
Prepared By:	Sabyasachi Roy, Ph.D. Sr. Director Regulatory Affairs, Quality Assurance & Compliance
Device Proprietary Name:	BrainScope TBI (Model: Ahead 500)
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 Device:	BrainScope TBI (model: Ahead 400) (K183241)

[1] Prepared in accordance with 21 CFR § 807.87(h) and 21 CFR § 807.92(c).

Device Description:

BrainScope TBI (model: Ahead 500) 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 concussion / mild traumatic brain injury (mTBI). The BrainScope TBI includes a new multivariate classification algorithm that analyzes a patient's electroencephalogram (EEG), augmented by neurocognitive performance and selected clinical symptoms to compute a multi-modal index called the Concussion Index (CI). BrainScope TBI provides the healthcare provider with a multi-parameter measure to aid in the evaluation of concussion following a head injury within the past 72 hours (3 days). The BrainScope TBI (Ahead 500) retains all the capabilities of the predicate (BrainScope TBI, model: Ahead 400) including the Structural Injury Classification (SIC) and the Brain Function Index (BFI). It also contains configurable, selectable computerized cognitive performance tests and digitized standard clinical assessment tools intended to provide a multi-modal panel of measures to support the clinical assessment of concussion / mTBI.

Indications for Use:[2]

The BrainScope TBI's Indications for Use are as follows:

- BrainScope TBI is a multi-modal, multi-parameter assessment indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury, and have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion/mild traumatic brain injury (mTBI)).
- BrainScope TBI provides a multi-parameter measure (Concussion Index (CI)) to aid in the evaluation of concussion in patients between the ages of 13–25 years who present with a GCS score of 15 following a head injury within the past 72 hours (3 days), in conjunction with a standard neurological assessment of concussion. The CI is computed from a multivariate algorithm based on the patient's electroencephalogram (EEG), augmented by neurocognitive measures and selected clinical symptoms.
- The BrainScope TBI Structural Injury Classification ("SIC") uses brain electrical activity (EEG) to determine the likelihood of structural brain injury visible on head CT for patients between the ages of 18-85 years (have a GCS score of 13 – 15), have sustained a closed head injury within the past 72 hours (3 days) who are being considered for a head CT. BrainScope TBI should not be used as a substitute for a CT scan. Negative likely corresponds to those with no structural brain injury visible on head CT. Positive likely corresponds to those with a structural brain injury visible on head CT. Equivocal may correspond to structural

[2] The differences between the BrainScope TBI and its predicate do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. The subject and predicate device have the same overall intended use.

brain injury visible on head CT or may indicate the need for further observation or evaluation.

- BrainScope TBI provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG), aiding in the evaluation of head injury as part of a multi-modal, multi-parameter assessment, in patients 18-85 years of age (have a GCS score of 13 – 15) who have sustained a closed head injury within the past 72 hours (3 days).
- The BrainScope TBI 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 BrainScope TBI 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.
- BrainScope TBI also provides clinicians with quantitative measures of cognitive performance in patients 13-85 years of age to aid in the assessment of an individual's level of cognitive function. These measures interact with the CI and can be used stand alone.
- BrainScope TBI 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 device

Proposed Device: BrainScope TBI, model Ahead 500 (TBD)	**Primary Predicate: BrainScope TBI, model Ahead 400 (K183241)**	**Comments**
BrainScope TBI is a multi-modal, multi-parameter assessment indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury, and have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion/mild traumatic brain injury (mTBI)).	BrainScope TBI is a multi-modal, multi-parameter assessment indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury within the past 72 hours (3 days), are between the ages of 18-85 years, have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion / mild traumatic brain injury	Equivalent. Moved patient age range and 72 hour time frame to SIC and BFI specific statements below. Moved statement regarding substitute for a CT scan to the SIC specific statement below.

Proposed Device: BrainScope TBI, model Ahead 500 (TBD)	Primary Predicate: BrainScope TBI, model Ahead 400 (K183241)	Comments
	(mTBI)), and are being considered for a head CT. BrainScope TBI should not be used as a substitute for a CT scan.	
BrainScope TBI provides a multi-parameter measure (Concussion Index (CI)) to aid in the evaluation of concussion in patients between the ages of 13–25 years who present with GCS of 15 following a head injury within the past 72 hours (3 days), in conjunction with a standard neurological assessment of concussion. The CI is computed from a multivariate algorithm based on the patient's electroencephalogram (EEG), augmented by neurocognitive measures and selected clinical symptoms.	BrainScope TBI provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG), aiding in the evaluation of head injury as part of a multi-modal, multi-parameter assessment.	Equivalent. The CI algorithm augments patient's EEG measures with neurocognitive performance and selected clinical symptoms to compute a multi-modal index. This is consistent with current clinical practice of using a multi-modal approach in concussion evaluation. The CI expands upon the clinical performance of the BFI by assessing presence of concussion at time of injury.
The BrainScope TBI Structural Injury Classification ("SIC") uses brain electrical activity (EEG) to determine the likelihood of structural brain injury visible on head CT for patients between the ages of 18-85 years (have a GCS score of 13 – 15), have sustained a closed head injury within the past 72 hours (3 days) who are being considered for a head CT. BrainScope TBI should not be used as a substitute for a CT scan. Negative likely corresponds to those with no structural brain injury visible on head CT. Positive likely corresponds to those with a structural brain injury visible	The BrainScope TBI Structural Injury Classification ("SIC") uses brain electrical activity to determine the likelihood of structural brain injury visible on head CT. Negative likely corresponds to those with no structural brain injury visible on head CT. Positive likely corresponds to those with a structural brain injury visible on head CT. Equivocal may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.	Equivalent. Included patient age range, GCS score, 72 hour timeframe and statement regarding substitute for a CT scan to the BrainScope TBI (Ahead 500) IFU for clarification.

Proposed Device: BrainScope TBI, model Ahead 500 (TBD)	Primary Predicate: BrainScope TBI, model Ahead 400 (K183241)	Comments
on head CT. Equivocal may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.		
BrainScope TBI provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG), aiding in the evaluation of head injury as part of a multi-modal, multi-parameter assessment, in patients 18-85 years of age (have a GCS score of 13 – 15) who have sustained a closed head injury within the past 72 hours (3 days).	BrainScope TBI provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG), aiding in the evaluation of head injury as part of a multi-modal, multi-parameter assessment.	Equivalent. Age range, GCS score and 72 hour timeframe added to the BrainScope TBI (Ahead 500) IFU for clarification.
The BrainScope TBI 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 BrainScope TBI 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 BrainScope TBI 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 BrainScope One 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.	Same as predicate.
BrainScope TBI also provides clinicians with quantitative measures of	BrainScope TBI also provides clinicians with quantitative measures of	Equivalent. Ahead 500 IFU statement was modified in two ways:

Proposed Device: BrainScope TBI, model Ahead 500 (TBD)	Primary Predicate: BrainScope TBI, model Ahead 400 (K183241)	Comments
cognitive performance in patients 13-85 years of age to aid in the assessment of an individual's level of cognitive function. These measures interact with the CI and can be used stand alone.	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.	• Specifying the intended age group of 13-85 years as cleared under predicate's 510(k) K183241. • Clarification that since the CI includes cognitive performance inputs and they do interact with EEG measures to produce CI. The cognitive performance assessments can also be used standalone.
BrainScope TBI 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.	BrainScope TBI 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.	Same as predicate.

Comparison of Technological Characteristics with the Predicate Device:

BrainScope TBI (model: Ahead 500) has similar technological characteristics as the legally marketed predicate device. BrainScope TBI includes the following modifications when compared to the predicate (BrainScope TBI, model: Ahead 400):

- The Concussion Index (CI) is derived from a multivariate classification algorithm that analyzes a patient's EEG, augmented by neurocognitive performance and selected clinical symptoms to compute a multi-modal index for patients 13 – 25 years of age, with a GCS of 15. The CI aids the trained healthcare provider in evaluating a patient for concussion within 3 days of head injury.

The EEG-based Structural Injury Classification (SIC) and Brain Function Index (BFI) algorithms in both devices are limited to the FDA-authorized age range of 18 to 85 years (Adolescent subgroup and Adult age patients).

The minor technological differences between BrainScope TBI (Ahead 500) and the predicate do not raise new questions of safety and effectiveness, and performance data demonstrates that the BrainScope TBI is as safe and effective as the predicate.

BrainScope TBI (Ahead 500) is substantially equivalent to the predicate BrainScope TBI (Ahead 400).

Table 2, Technological Comparison to Predicate Device

Topic / Area	Proposed Device: BrainScope TBI, model : Ahead 500	Predicate: BrainScope TBI, model: Ahead 400 (K183241)	Comments
Platform	Trimble T41 mobile device, Android OS	Trimble T41 mobile device, Android OS	Same as predicate.
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 0.67Hz to 43Hz bandwidth	Same as predicate.
Common Mode Rejection Ratio (CMRR)	< -100 dB (or better)	< -100 dB (or better)	Same as predicate.
System Noise Floor	< 0.4 µV in 0.67 Hz to 43Hz bandwidth	< 0.4 µV in 0.3 Hz to 43Hz bandwidth	Same as predicate.
ADC Resolution	45 nV/bit	45 nV/bit	Same as predicate.
ADC Sampling Rate	1000 Hz, down sampled to 100 Hz for algorithm processing	1000 Hz, down sampled to 100 Hz for algorithm processing	Same as predicate.
Electrode Placement System	The International 10-20 System	The International 10-20 System	Same as predicate.
Electrode Positions Utilized	Fp1, Fp2, Fpz, AFz, F7, F8, A1, A2	Fp1, Fp2, Fpz, Afz, F7, F8, A1, A2	Same as predicate.
Electrode Material	Single use Ag/AgCl electrode sensor array headset with solid gel	Single use Ag/AgCl electrode sensor array headset with solid gel	Same as predicate.
Real Time EEG Display	Yes	Yes	Same as predicate.
EEG Based Classification Algorithms	• SIC with three tier classification outputs (Negative, Equivocal and Positive) • BFI • CI	• SIC with three tier classification outputs (Negative, Equivocal and Positive) • BFI	Equivalent. Both devices share identical SIC and BFI algorithms. In addition, the BrainScope TBI (Ahead 500) includes the new multivariate algorithm to compute CI.

Topic / Area	Proposed Device: BrainScope TBI, model : Ahead 500	Predicate: BrainScope TBI, model: Ahead 400 (K183241)	Comments
Cognitive Performance Tests	• Procedural Reaction Time • Match to Sample • Simple Reaction Time • Go/No-Go • Simple Reaction Time Test Repeated Device has ability to compare patient's cognitive performance and produce a Reliable Change Index (RCI). Tests include Adolescent and Adult ages of 13 – 85 years.	• Procedural Reaction Time • Match to Sample • Simple Reaction Time • Go/No-Go • Simple Reaction Time Test Repeated Device has ability to compare patient's cognitive performance and produce a Reliable Change Index (RCI). Tests include Adolescent and Adult ages of 13 – 85 years.	Same as predicate.
Standard Clinical Assessments	Multiple electronic version of "paper and pencil" based standard clinical assessments of concussion such as: • PECARN	Multiple electronic version of "paper and pencil" based standard clinical assessments of concussion such as: • PECARN	Equivalent.
Results Presentation and Reporting Features	Specific raw measures. EEG playback. Structural injury classification, brain function index (BFI) Concussion Index (CI) display. Cognitive performance raw and standard scores including percentiles. Electronic versions of Standard Clinical Assessments.	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.	Equivalent. BrainScope TBI (Ahead 500) includes additional CI related results and reporting.
Software	BrainScope TBI implements its software with low-level modifications to the T41's off-the-shelf configuration and a kiosk mode application running on Android 4.1.	BrainScope TBI implements its software with low-level modifications to the T41's off-the-shelf configuration and a kiosk mode application running on Android 4.1.	Equivalent. Updated architecture to improve device maintainability, scalability and to support the new CI functionality.
Graphical User Interface	BrainScope developed UI leveraging Android Frameworks.	BrainScope developed UI leveraging Android Frameworks.	Equivalent. New CI functionality included.

Topic / Area	Proposed Device: BrainScope TBI, model : Ahead 500	Predicate: BrainScope TBI, model: Ahead 400 (K183241)	Comments
Test Reporting	Test output for EEG and standardized assessments can be configured to meet user requirements including disabling tests and redaction of personally identifiable information	Test output for EEG and standardized assessments can be configured to meet user requirements including disabling tests and redaction of personally identifiable information	Same as predicate.
Data Management	All data stored (binary format) to non-volatile memory. Data available via USB and wireless connection. Certificate based authentication for wireless communication	All data stored (binary format) to non-volatile memory. Data available via USB and wireless connection.	Equivalent. BrainScope TBI (model: Ahead 500) enables secure communication with cloud based infrastructure to support data synchronization.
Connectivity	• USB 2.0 Full-Speed • GPS • Wi-Fi: 802.11b/g/n, 2.4 GHz band • All other interfaces disabled in software	• USB 2.0 Full-Speed • GPS • Wi-Fi: 802.11b/g/n, 2.4 GHz band • All other interfaces disabled in software	Equivalent.
Encryption	AES-128 for intra-device communication AES-256 for encrypted files	AES-128 for intra-device communication AES-256 for encrypted files	Same as predicate.

Performance Data:

Clinical performance data was submitted to support the device modification made to the predicate. Validation data analysis was performed on 580 subjects across 10 US clinical sites including High Schools, Colleges and Concussion Clinics. The validation study population included subjects ages 13.09 - 25.93 years, with mean=19.52 (SD=2.28, median=19.71), 53.62% male, with a mean time since injury for Day 0 evaluation was 45.75 hours (SD=22.66, median=47.75). All subjects had GCS score of 15. Of these 580 subjects, there were 229 matched controls, 144 healthy volunteers and 207 subjects who sustained closed head injury and were removed from play. These subjects were divided into 3 groups: healthy, non-head injured subjects (pre-season baselines only), subjects with witnessed head injury, and matched controls (tested at 3 time points relative to those of their injured matched subject). Device performance was studied in subjects who were either removed from play, and were therefore deemed to have had a concussion, or were matched controls and healthy volunteers. The clinical reference standard incorporated elements from the guidelines published in International Conference on Concussion in

Sport guidelines (McCrory 2017;2013) as well as National Collegiate Athletic Association (NCAA) concussion policy.

The co-primary endpoints of the study were the sensitivity and specificity based on a cutoff (threshold) CI derived from an algorithm development study that was independent of the validation study. The validation study sought to determine if the subject's CI was consistent with similar changes seen in subjects with concussion. This primary endpoint validates the clinical utility of the EEG-based, multimodal Concussion Index (CI) as an aid in evaluation of concussion in subjects ages 13-25 years who sustained a closed head injury.

The performance goals that were defined in the Statistical Analysis Plan (SAP) for the co-primary endpoints were 0.69 for sensitivity and 0.565 for specificity. The observed performance of the CI in the clinical validation study was sensitivity of 0.8599 with 95% confidence limits of (0.8050, 0.9041) and specificity of 0.7078 with 95% confidence limits of (0.6588, 0.7535).

Analysis of the study results demonstrated that the change in CI over time, measured at a population level in the non-head injured population, demonstrate that the CI is a stable measure and that the change can be interpreted reliably.

The validation study achieved the pre-specified performance targets for the primary endpoint. Additional analyses demonstrated that the CI discriminant score and the 22-question Concussion Symptom Inventory (CSI) total score had a correlation of ($r = 0.7971$, $R^2 = 0.6354$). The CI and the 12-question CSI total score had a correlation of ($r = 0.8047$, $R^2 = 0.6475$).

These new modifications did not impact existing device functionality including core EEG based Structural Injury Classifier (SIC) and Brain Function Index (BFI) algorithms. The BrainScope TBI device conforms to all basic safety and EMC standards as the predicate. The BrainScope TBI device was also tested to the most recent recognized consensus standard for EMC (IEC 60601-1-2 Ed. 4.0 2014) as shown below.

The BrainScope TBI device conforms to the following standards:

- IEC 60601-1/A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Edition 4.0 2014 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - 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

Conclusion:

The BrainScope TBI (model: Ahead 500) device has the same intended use as the legally marketed predicate (BrainScope TBI, model: Ahead 400). The BrainScope TBI device has similar technological characteristics as the predicate. The differences in technological characteristics do not raise new questions of safety and effectiveness and performance data demonstrate that the BrainScope TBI (Ahead 500) is as safe and effective as the predicate.