February 19, 2019

BrainScope Company Inc.
Michael Singer
CEO
4350 East West Hwy, Ste 1050
Bethesda, Maryland 20814

Re: K183241
Trade/Device Name: BrainScope TBI (Model: Ahead 400)
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: November 20, 2018
Received: November 21, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 R. Gupta -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183241

Device Name
BrainScope TBI (Model: Ahead 400)

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 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 (mTBI)), and are being considered for a head CT. BrainScope TBI should not be used as a substitute for a CT scan.

• 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.

• 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.

• 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 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.

• 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. Chief Executive Officer BrainScope Company, Inc. Phone: (240) 752-7677 Fax: (240) 752-7679 Email: michael.singer@brainscope.com
Prepared By:	Sabyasachi Roy, Ph.D. Director Regulatory Affairs, Quality Assurance & Compliance
Device Proprietary Name:	BrainScope TBI (Model: Ahead 400)
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 One (K181179) ANAM Test System: Military Battery (K150154)

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

Device Description:

BrainScope TBI 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 mild traumatic brain injury (mTBI). It also contains configurable, selectable computerized cognitive performance tests and digitized standard clinical assessment intended to provide a multi-modal panel of measures to support the clinical assessment of concussion / mTBI. BrainScope TBI provides healthcare professionals with a set of validated and clinically accepted library of concussion / mTBI assessments.

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 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 (mTBI)), and are being considered for a head CT. BrainScope TBI should not be used as a substitute for a CT scan.
- 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.
- 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.
- 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 to aid in the assessment of an individual's level of cognitive function.

[2] The differences between the BrainScope TBI and its predicate (BrainScope One) 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.

These measures 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.

Table 1: Indications for Use Comparison to Predicate devices

Proposed Device: BrainScope TBI (K183241)	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	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 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 (mTBI)), and are being considered for a head CT. BrainScope TBI should not be used as a substitute for a CT scan.	BrainScope One 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 (including concussion / mild Traumatic Brain Injury (mTBI)), and are between the ages of 18-85 years. BrainScope One should not be used as a substitute for a CT scan.	N/A	Equivalent. As cleared under 510(k) K181785.
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	The BrainScope One 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	N/A	Same as primary predicate.

Proposed Device: BrainScope TBI (K183241)	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	Comments
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.	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 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.	A negative BrainScope One 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.	N/A	Equivalent. As cleared under 510(k) K181785.
	A positive BrainScope One 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.	N/A	Equivalent. As cleared under 510(k) K181785.
	An equivocal BrainScope One Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72	N/A	Equivalent. As cleared under 510(k) K181785.

Proposed Device: BrainScope TBI (K183241)	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	Comments
	hours, 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.	The BrainScope One provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG).	N/A	Equivalent. As cleared under 510(k) K181785.
BrainScope TBI 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 BrainScope One 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 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 evaluating cognitive function.	Same as primary predicate (BrainScope One) and equivalent to secondary predicate (ANAM Test System – Military Battery). BrainScope TBI extends age range from 18-85 years in predicate (BrainScope One) to 13 – 85 years. Additional performance data including norming study supported the extended age range.
BrainScope TBI also stores and displays electronic versions of standardized clinical assessment tools that should be used in	The BrainScope One also stores and displays electronic versions of standardized clinical assessment tools that	N/A	Equivalent. Expanding the availability of clinical assessment tools does not affect the

Proposed Device: BrainScope TBI (K183241)	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	Comments
accordance with the assessment tools' general instructions. These tools do not interact with any other device measures, and are stand alone.	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.		safety and effectiveness of the device. Expanding functionality increases the utility of the device and better meets user needs.

Comparison of Technological Characteristics with the Predicate Device:

The BrainScope TBI has similar technological characteristics as the legally marketed predicate devices. The BrainScope TBI includes the following modifications when compared to the primary predicate (BrainScope One):

- Three additional computerized Cognitive Performance tests for a total of five. All five computerized Cognitive Performance tests are intended for use on patients 13 – 85 years of age.
- The addition of PECARN – Pediatric Head Injury Predication Rule to the library of Standard Clinical Assessments already included in BrainScope One.
- Expanded device connectivity to include an Over the Air (OTA) software upgrade capability made possible using a Wi-Fi or Cellular connection.

All EEG based 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 the BrainScope TBI and the predicates do not raise new questions of safety and effectiveness and performance data demonstrate that the BrainScope TBI is as safe and effective as the predicate.

The BrainScope TBI is substantially equivalent to the predicates the BrainScope One and ANAM Test System – Military Battery.

Table 2, Technological Comparison to Predicate Device

Topic / Area	Proposed Device: BrainScope TBI	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	Comments
Hardware				
Platform	Trimble T41 mobile device, Android OS	Trimble T41 mobile device, Android OS	PC: Dell Latitude E6440 Laptop	Same as primary predicate.

Topic / Area	Proposed Device: BrainScope TBI	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	Comments
			Computer, two button USB connected mouse, and Windows 7 Operating System	
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	N/A	Same as primary predicate.
Common Mode Rejection Ratio (CMRR)	< -100 dB (or better)	< -100 dB (or better)	N/A	Same as primary predicate.
System Noise Floor	< 0.4 µV in 0.67 Hz to 43Hz bandwidth	< 0.4 µV in 0.3 Hz to 43Hz bandwidth	N/A	Same as primary predicate.
ADC Resolution	45 nV/bit	45 nV/bit	N/A	Same as primary predicate.
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	Same as primary predicate.
Electrode Placement System	The International 10-20 System	The International 10-20 System	N/A	Same as primary predicate.
Electrode Positions Utilized	Fp1, Fp2, Fpz, AFz, F7, F8, A1, A2	Fp1, Fp2, Fpz, Afz, F7, F8, A1, A2	N/A	Same as primary 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	N/A	Same as primary predicate.
Assessment and Software				
Real Time EEG Display	Yes	Yes	N/A	Same as primary predicate.
EEG Based Classificati	Three tier classification with results of	Three tier classification with results of	N/A	Same as primary predicate.

Topic / Area	Proposed Device: BrainScope TBI	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	Comments
on Algorithm (Structural Injury Classification)	Negative, Equivocal and Positive outputs.	Negative, Equivocal and Positive outputs.		Both devices also implement same EEG based Brain Function Index (BFI) algorithms which are different from the SIC algorithms. Both devices also share the same 8-types of EEG artifacting algorithms.
Cognitive Performance Tests	• Procedural Reaction Time • Matching 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 • Matching to Sample No ability in device software to automatically compare two tests but this can be done by clinician manually. No RCI output. Tests are for Adolescent and Adult ages of 18 – 85 years.	Modules include: • Demographics • Sleepiness Scale • Symptoms Checklist • Mood Scale • TBI Questionnaire • Simple Reaction Time • Code Substitution – Learning • Procedural Reaction Time • Mathematical Processing • Matching to Sample • Code Substitution – Delayed • Simple Reaction Time (R) Device has ability to compare patient's cognitive performance and	Equivalent. New tests and RCI output included in BrainScope TBI are well accepted in clinical practice for assessment of Adult and Adolescent patient population.

Topic / Area	Proposed Device: BrainScope TBI	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	Comments
			produce a Reliable Change Index (RCI). Tests are for Adolescent and Adult ages of 18 – 65 years.	
Standard Clinical Assessments	Multiple electronic version of "paper and pencil" based standard clinical assessments such as: • Concussion Symptom Inventory (CSI) • Graded Symptom Checklist (GSC) • Sports Concussions Assessment Tool- 3rd Edition (SCAT3) • Sports Concussions Assessment Tool- 5th Edition (SCAT5) • National Football League - Sports Concussions Assessment Tool (NFL SCAT) • Standard Assessment of Concussion - 2nd Edition (SAC) • Military Acute Concussion Evaluation (MACE) • PECARN	Multiple electronic version of "paper and pencil" based standard clinical assessments such as: • Concussion Symptom Inventory (CSI) • Graded Symptom Checklist (GSC) • Sports Concussions Assessment Tool- 3rd Edition (SCAT3) • Sports Concussions Assessment Tool- 5th Edition (SCAT5) • National Football League - Sports Concussions Assessment Tool (NFL SCAT) • Standard Assessment of Concussion - 2nd Edition (SAC) • Military Acute Concussion Evaluation (MACE) • Others	N/A	Equivalent. PECARN added to existing library of digitized Standard Clinical Assessment.

Topic / Area	Proposed Device: BrainScope TBI	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	Comments
	• Others			
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 and brain function index display. Cognitive performance raw and standard scores including percentiles. Electronic versions of Standard Clinical Assessments.	• No EEG • No Standard Clinical Assessments • 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.	Equivalent. BrainScope TBI includes additional Cognitive Performance tests.
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 One 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.	PC: Dell Latitude E6440 Laptop Computer, two button USB connected mouse, and Windows 7 Operating System	Equivalent. Same architecture and implementation. Software can be updated over the air (OTA).
Graphical User Interface	BrainScope developed UI leveraging Android Frameworks.	BrainScope developed UI leveraging Android Frameworks.	Custom GUI on Windows 7 Operating System	Same as primary predicate.

Topic / Area	Proposed Device: BrainScope TBI	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	Comments
Test Reporting	PDF report generation for facilitating printing out as paper record per user discretion Test output for EEG and standardized assessments can be configured to meet user requirements including disabling tests and redaction of personally identifiable information	PDF report generation for facilitating printing out as paper record per user discretion Test output for EEG and standardized assessments can be configured to meet user requirements including disabling tests and redaction of personally identifiable information	N/A	Same as primary predicate.
Data Management	All data stored (binary format) to non-volatile memory. Data available via USB and wireless connection.	All data stored (binary format) to non-volatile memory. Data available via USB connection or SD card removal.	Standard PC	Equivalent. BrainScope TBI has additional data transfer capabilities using wireless connection.
Connectivity	• USB 2.0 Full-Speed • GPS • Cellular: UMTS/HSPA+: B1, B2, B5, B6, B8; GSM/GPRS/EDGE: 850, 900, 1800, 1900 MHz bands; • Wi-Fi: 802.11b/g/n, 2.4 GHz band • All other interfaces disabled in software	• USB 2.0 Full-Speed • GPS • All other interfaces disabled in software	Standard PC	Equivalent. BrainScope TBI has wireless connectivity to accept Over the Air (OTA) software upgrades.
Encryption	AES-128 for intra-device communication	AES-128 for intra-device communication	N/A	Same as primary predicate.

Topic / Area	Proposed Device: BrainScope TBI	Primary Predicate: BrainScope One (K181179)	Secondary Predicate: ANAM Test System – Military Battery (K150154)	Comments
	AES-256 for encrypted files	AES-256 for encrypted files		

Performance Data:

Performance data was submitted to support the device modification made to the predicate. Normative data was collected from 707 healthy individuals with age range of 13-85 years to construct databases for the cognitive tests implemented on the BrainScope TBI. Test data demonstrated that the modifications made to the predicate namely – additional cognitive performance tests, additional standard clinical assessment (PECARN) and wireless connectivity are implemented as per specifications. These new modifications did not impact existing device functionality including core EEG based algorithms. The BrainScope TBI device conforms to all same 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 device has the same intended use as the legally marketed primary predicate (BrainScope One) and secondary predicate (ANAM Test System – Military Battery). The BrainScope TBI device has similar technological characteristics as the predicates. The minor differences in technological characteristics do not raise new questions of safety and effectiveness and performance data demonstrate that the BrainScope TBI is as safe and effective as the predicates.