

Indications for Use

510(k) Number (if known)

K181179

Device Name

BrainScope One

Indications for Use (Describe)

- 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. The BrainScope One should not be used as a substitute for a CT scan.
- 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 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 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.
- 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.
- An equivocal BrainScope One 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 BrainScope One provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG).
- 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.
- BrainScope One 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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