FDA 510(k) Premarket Notification

K190815 BrainScope TBI

CLEARED

Sep 11, 2019
166 days to decision

K190815 · Product code: **PIW** · Neurology
Source: https://www.510kdatabase.net/k190815/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid (PIW)
Date received	Mar 29, 2019
Decision date	Sep 11, 2019
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brainscope Company, Inc.**
Location	Washington, DC, US
Contact	Michael Singer
510(k) history	8 submissions · 7 cleared · 2009-2019

CLINICAL EVIDENCE - NCT02477943

Objective Brain Function Assessment of mTBI/Concussion in College Athletes

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	520 patients (actual)
Study sites	11 sites
Condition studied	Brain Injuries, Traumatic; Concussion, Mild; Concussion, Brain; Concussion, Intermediate; Concussion, Severe
Study type	Observational
Completion date	Jul 31, 2017
Sponsor	BrainScope Company, Inc. (Industry)

Primary outcome

Algorithm for Likelihood of being concussed

Secondary outcome

Advanced Neuroimaging in concussion

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02477943