FDA 510(k) Premarket Notification

K183241 BrainScope TBI (Model: Ahead 400)

CLEARED

Feb 19, 2019
90 days to decision

K183241 · Product code: **PIW** · Neurology
Source: https://www.510kdatabase.net/k183241/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid (PIW)
Date received	Nov 21, 2018
Decision date	Feb 19, 2019
Days to decision	90 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 E Singer
510(k) history	8 submissions · 7 cleared · 2009-2019