

**K183241 BrainScope TBI (Model: Ahead 400)**Feb 19, 2019  
90 days to decisionK183241 · Product code: **PIW** · Neurology  
Source: <https://www.510kdatabase.net/k183241/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183241/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 22, 2026