

**K181179 BrainScope One**May 18, 2018  
16 days to decisionK181179 · Product code: **PIW** · Neurology  
Source: <https://www.510kdatabase.net/k181179/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid (PIW)
Date received	May 2, 2018
Decision date	May 18, 2018
Days to decision	16 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/k181179/> 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