

K161068 Ahead 300Sep 22, 2016
160 days to decisionK161068 · Product code: **PIW** · Neurology
Source: <https://www.510kdatabase.net/k161068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid (PIW)
Date received	Apr 15, 2016
Decision date	Sep 22, 2016
Days to decision	160 days
Third-party review	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

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