

K181785 Modified BrainScope OneDec 19, 2018
169 days to decisionK181785 · Product code: **PIW** · Neurology
Source: <https://www.510kdatabase.net/k181785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid (PIW)
Date received	Jul 3, 2018
Decision date	Dec 19, 2018
Days to decision	169 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

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