

K182180 SPEAC SystemMay 11, 2019
271 days to decisionK182180 · Product code: **POS** · Neurology
Source: <https://www.510kdatabase.net/k182180/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Physiological Signal Based Seizure Monitoring System (POS)
Date received	Aug 13, 2018
Decision date	May 11, 2019
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Brain Sentinel, Inc.
Location	San Antonio, TX, US
Contact	Richard Waite
510(k) history	2 submissions · 2 cleared · 2019-2021

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