

K200276 SPEAC SystemFeb 6, 2021
368 days to decisionK200276 · Product code: **POS** · Neurology
Source: <https://www.510kdatabase.net/k200276/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Physiological Signal Based Seizure Monitoring System (POS)
Date received	Feb 4, 2020
Decision date	Feb 6, 2021
Days to decision	368 days
Third-party review	No
Combination product	No
PCCP authorized	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

CLINICAL EVIDENCE - NCT01874600**Seizure Detection and Warning System for Epilepsy Patients**

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	239 patients (actual)
Study sites	1 site
Condition studied	Epilepsy
Study type	Observational
Completion date	Dec 1, 2019
Sponsor	Brain Sentinel (Other)

Primary outcome

Primary outcome is accuracy of device to detect GTC seizures when compared to video EEG.

Secondary outcome

Comparison of study device to self reporting of seizures using a seizure diary.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT01874600

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k200276/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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