

K231779 REMI AI Discrete Detection ModuleJan 3, 2024
201 days to decisionK231779 · Product code: **OMB** · Neurology
Source: <https://www.510kdatabase.net/k231779/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Jun 16, 2023
Decision date	Jan 3, 2024
Days to decision	201 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Epitel, Inc.
Location	Salt Lake City, UT, US
Contact	Christopher Phillips
510(k) history	4 submissions · 4 cleared · 2021-2024

CLINICAL EVIDENCE - NCT03583957**A Wireless EEG Patch for Continuous Electrographic Monitoring**

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	750 patients (estimated)
Study sites	3 sites
Condition studied	Epilepsy
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Apr 30, 2026
Sponsor	Epitel, Inc. (Industry)

Primary outcome

Single channel EEG coherence

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03583957510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231779/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026