

K243185 REMI Remote EEG Monitoring SystemMar 21, 2025
172 days to decisionK243185 · Product code: **OMC** · Neurology
Source: <https://www.510kdatabase.net/k243185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced- Montage Standard Electroencephalograph (OMC)
Date received	Sep 30, 2024
Decision date	Mar 21, 2025
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Epitel
Location	Salt Lake City, UT, US
Contact	Christopher Phillips
510(k) history	1 submissions · 1 cleared · 2025-2025

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