

K240408 REMI-AI Rapid Detection Module (REMI-AI RDM)

Oct 17, 2024
251 days to decision

K240408 · Product code: **OMB** · Neurology
Source: <https://www.510kdatabase.net/k240408/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Feb 9, 2024
Decision date	Oct 17, 2024
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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