FDA 510(k) Premarket Notification

K251726 SignalNED System (Model RE)

CLEARED

Sep 3, 2025
90 days to decision

K251726 · Product code: **OMC** · Neurology
Source: https://www.510kdatabase.net/k251726/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced- Montage Standard Electroencephalograph (OMC)
Date received	Jun 5, 2025
Decision date	Sep 3, 2025
Days to decision	90 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Forest Devices, Inc.**
Location	Pittsburgh, PA, US
Contact	Carmelo Montalvo
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov