

K253607 UNEEG EpiSight SystemJun 11, 2026
205 days to decisionK253607 · Product code: **SEM** · Neurology
Source: <https://www.510kdatabase.net/k253607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sub-scalp Implanted Electroencephalogram System For Remote Patient Monitoring (SEM)
Date received	Nov 18, 2025
Decision date	Jun 11, 2026
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Uneeg Medical A/S
Location	Alleroed, DK
Contact	Camilla Wismar
510(k) history	1 submissions · 1 cleared · 2026-2026

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