

K253668 Onera SleepMap (SLEEPMAP)Mar 8, 2026
107 days to decisionK253668 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k253668/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Nov 21, 2025
Decision date	Mar 8, 2026
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Onera B.V.
Location	Eindhoven, NL
Contact	Pieter Ermers
510(k) history	4 submissions · 4 cleared · 2022-2026

CLINICAL EVIDENCE - NCT05310708**Validation Study of a Patch-based PSG System**

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	300 patients (estimated)
Study sites	7 sites
Condition studied	Sleep Disorder
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 21, 2024
Sponsor	Onera BV (Industry)

Primary outcome

EOG left

Secondary outcome

Total Sleep Time

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05310708