

K243199 NightWatch+ USJul 12, 2025
284 days to decisionK243199 · Product code: **POS** · Neurology
Source: <https://www.510kdatabase.net/k243199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Physiological Signal Based Seizure Monitoring System (POS)
Date received	Oct 1, 2024
Decision date	Jul 12, 2025
Days to decision	284 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Livassured BV
Location	Leiden, NL
Contact	Jolanda Oorthuizen
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243199/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026