

K240700 HomeSleepTest (HST, HST REM+)Dec 8, 2024
269 days to decisionK240700 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k240700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Mar 14, 2024
Decision date	Dec 8, 2024
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Somnomedics GmbH
Location	Washington, DC, US
Contact	Cherita James
510(k) history	7 submissions · 7 cleared · 2007-2024

REGULATORY CONSULTANT

Consulting firm	Propharma Group
Contact	Cherita James

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240700/> 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