FDA 510(k) Premarket Notification

CLEARED

K240700 HomeSleepTest (HST, HST REM+)

Dec 8, 2024
269 days to decision

K240700 · 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