FDA 510(k) Premarket Notification

K242290 DormoTech NLab

CLEARED

Jan 8, 2025
159 days to decision

K242290 · Product code: **MNR** · Neurology
Source: https://www.510kdatabase.net/k242290/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Aug 2, 2024
Decision date	Jan 8, 2025
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dormotech Medical, Ltd.**
Location	Afula, IL
Contact	Abed Nassir
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**ProMedic Consulting, LLC**
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT06224972

Evaluation of the Usability and Performance Assessment of the DormoTech VLAB Device as a Home Sleep Test

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	47 patients (actual)
Study sites	1 site
Condition studied	Sleep Disorder
Study type	Observational
Completion date	Aug 12, 2023
Sponsor	Dormotech Medical (Industry)

Primary outcome

AHI Score and Classification

Secondary outcome

Total Sleep Time (min)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06224972