FDA 510(k) Premarket Notification

K251770 SleepRes PAP System

CLEARED

Dec 15, 2025
188 days to decision

K251770 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k251770/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jun 10, 2025
Decision date	Dec 15, 2025
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sleepres, Inc.**
Location	Murfreesboro, TN, US
Contact	John Columbo
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

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

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