FDA 510(k) Premarket Notification

K251847 Sleepnet Arie Full Face Vented Mask

CLEARED

Jan 15, 2026
213 days to decision

K251847 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k251847/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jun 16, 2025
Decision date	Jan 15, 2026
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sleepnet Arie Nasal Vented Mask

APPLICANT

Company	**Sleepnet Corporation**
Location	Manchester, NH, US
Contact	Jennifer Kennedy
510(k) history	23 submissions · 23 cleared · 1996-2026

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Todd Courtney

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