FDA 510(k) Premarket Notification

K241830 Mojo Full Face Vented Mask

CLEARED

Oct 18, 2024
116 days to decision

K241830 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k241830/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jun 24, 2024
Decision date	Oct 18, 2024
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Veraseal 2 Full Face Vented Mask; Innova Full Face Vented Mask; Ascend Full Face 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	**ProMedic, LLC**
Contact	Paul Dryden

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