FDA 510(k) Premarket Notification

K241943 Mojo Full Face Non-Vented Mask

CLEARED

Aug 28, 2024
57 days to decision

K241943 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k241943/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jul 2, 2024
Decision date	Aug 28, 2024
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Veraseal 2 Full Face Non-Vented Mask; Veraseal 2 Full Face AAV Non-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