

K190254 Mojo 2 Full Face Vented Mask, Veraseal 3 Full Face Vented Mask, V3 Full Face Vented MaskJul 5, 2019
148 days to decisionK190254 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k190254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Feb 7, 2019
Decision date	Jul 5, 2019
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190254/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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