

K203601 Innova Nasal Non-Vented MaskApr 30, 2021
142 days to decisionK203601 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k203601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 9, 2020
Decision date	Apr 30, 2021
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Sleepnet Corporation % Promedic, LLC
Contact	Paul Dryden

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

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