

**K211274 iQ 2 Nasal Mask, Phantom 2 Nasal Mask**Jan 10, 2022  
258 days to decisionK211274 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k211274/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Apr 27, 2021
Decision date	Jan 10, 2022
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sleepnet Corporation % Promedic, LLC</b>
Contact	Paul Dryden

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211274/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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