FDA 510(k) Premarket Notification

# K241469 iQ 2 Nasal Vented Mask

**CLEARED**

Jun 15, 2024
22 days to decision

K241469 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k241469/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received | May 24, 2024 |
| Decision date | Jun 15, 2024 |
| Days to decision | 22 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Phantom 2 Nasal Vented Mask |

## APPLICANT

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

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **ProMedic Consulting, LLC** |
| Contact | Paul Dryden |

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