

K253939 DeltaWave Nasal Pillow SystemJan 7, 2026
29 days to decisionK253939 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k253939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 9, 2025
Decision date	Jan 7, 2026
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	RemSleep Holdings, Inc.
Location	Blackshear, GA, US
Contact	Tom Wood
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	ProMedic, LLC
Contact	Anne Dryden Siegal

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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