

K982454 BIPAP VISION VENTILATORY SUPPORTNov 3, 1998
111 days to decisionK982454 · Product code: **MNT** · Anesthesiology
Source: <https://www.510kdatabase.net/k982454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use (MNT)
Date received	Jul 15, 1998
Decision date	Nov 3, 1998
Days to decision	111 days
Third-party review	No

APPLICANT

Company	Respironics, Inc.
Location	Monroeville, PA, US
Contact	DOUG MECHLENBURG
Website	https://www.respironics.com
510(k) history	172 submissions · 168 cleared · 1977-2024

Respironics, Inc. is an American medical supply company owned by Philips. It specializes in products that improve respiratory functions and is based in Monroeville, Pennsylvania. The company maintains a strong FDA 510(k) regulatory record spanning from 1977 to 2024. Respironics has received FDA 510(k) clearances from total submissions. The dominant focus is Anesthesiology devices, which represent approximately 90% of all submissions. The latest clearance in 2024 reflects continued regulatory activity. Recent cleared devices include masks, ventilators, and sleep therapy sy...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982454/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026