

**K121623 BIPAP A 40 VENTILATORY SUPPORT SYSTEM**Dec 14, 2012  
196 days to decisionK121623 · Product code: **MNT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k121623/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use (MNT)
Date received	Jun 1, 2012
Decision date	Dec 14, 2012
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Respironics, Inc.</b>
Location	Monroeville, PA, US
Contact	ELAINE LARKIN
Website	<a href="https://www.respironics.com">https://www.respironics.com</a>
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...

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