

**K030563 ARABELLA NCPAP MASKS**Sep 9, 2003  
200 days to decisionK030563 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k030563/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Feb 21, 2003
Decision date	Sep 9, 2003
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hamilton Medical AG</b>
Location	Reno, NV, US
Contact	J. DAVID THOMPSON
Website	<a href="http://www.hamilton-medical.com/">http://www.hamilton-medical.com/</a>
510(k) history	30 submissions · 30 cleared · 2003-2021

Hamilton Medical AG is a manufacturer of mechanical ventilation systems and respiratory care devices with a manufacturing facility in Reno, US. The company develops ventilators, oxygen therapy devices, and integrated accessories for critical care, emergency transport, and anesthesia applications. Hamilton Medical has received FDA 510(k) clearances from total submissions. The company specializes exclusively in Anesthesiology devices. FDA 510(k) clearances span from 2003 to 2021, establishing a strong regulatory track record over nearly two decades. Notable cleared devices ...

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