

**K052863 RAPHAEL COLOR**Jan 6, 2006  
87 days to decisionK052863 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k052863/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Oct 11, 2005
Decision date	Jan 6, 2006
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hamilton Medical AG</b>
Location	Reno, NV, US
Contact	CURDIN DANUSER
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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