

**K201306 HAMILTON-C3**Feb 5, 2021  
266 days to decisionK201306 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k201306/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	May 15, 2020
Decision date	Feb 5, 2021
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hamilton Medical AG</b>
Location	Reno, NV, US
Contact	Simone Haller
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 ...