

K071194 RAPHAEL COLOR ASV VENTILATOROct 18, 2007
171 days to decisionK071194 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k071194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Apr 30, 2007
Decision date	Oct 18, 2007
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hamilton Medical AG
Location	Reno, NV, US
Contact	JOERG SCHNEIDER
Website	http://www.hamilton-medical.com/
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 ...
