

K153046 HAMILTON-MR1Sep 6, 2016
323 days to decisionK153046 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k153046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Oct 19, 2015
Decision date	Sep 6, 2016
Days to decision	323 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hamilton Medical AG
Location	Reno, NV, US
Contact	KATRIN VOGT
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 ...
