

K163283 HAMILTON-H900, HAMILTON-BC8010, HAMILTON-BC4010Sep 20, 2017
303 days to decisionK163283 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k163283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Nov 21, 2016
Decision date	Sep 20, 2017
Days to decision	303 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hamilton Medical AG
Location	Reno, NV, US
Contact	Steffen Boden
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 ...

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Device record: <https://www.510kdatabase.net/k163283/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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