

K090468 HAMILTON-C2Jun 15, 2009
112 days to decisionK090468 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k090468/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Continuous, Facility Use (CBK) |
| Date received | Feb 23, 2009 |
| Decision date | Jun 15, 2009 |
| Days to decision | 112 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 ...
