

K241135 RESPOND(R) VentilatorNov 13, 2024
203 days to decisionK241135 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k241135/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Continuous, Facility Use (CBK) |
| Date received | Apr 24, 2024 |
| Decision date | Nov 13, 2024 |
| Days to decision | 203 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Corvent Medical, Inc. |
| Location | Fargo, ND, US |
| Contact | Richard Walsh |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------|
| Consulting firm | ProMedic, LLC |
| Contact | Paul Dryden |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241135/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026