

K100121 MODEL 300157 CPAP SYSTEMJul 13, 2010
179 days to decisionK100121 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k100121/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received | Jan 15, 2010 |
| Decision date | Jul 13, 2010 |
| Days to decision | 179 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Aeionmed, Inc. |
| Location | Stoughton, WI, US |
| Contact | DARIN BUSCH |
| 510(k) history | 4 submissions · 4 cleared · 2004-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100121/> 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 24, 2026