

**K132967 3B RESMART CPAP AND AUTO CPAP, BMC
RESMART CPAP AND AUTO CPAP**Dec 6, 2013
77 days to decisionK132967 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k132967/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received | Sep 20, 2013 |
| Decision date | Dec 6, 2013 |
| Days to decision | 77 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | 3B Medical, Inc. |
| Location | Lake Wales, FL, US |
| Contact | ALEX LUCIO |
| 510(k) history | 10 submissions · 10 cleared · 2013-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132967/> 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