

K032056 BILEVEL CPAP, MODEL 9055 SERIESFeb 20, 2004
233 days to decisionK032056 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k032056/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received | Jul 2, 2003 |
| Decision date | Feb 20, 2004 |
| Days to decision | 233 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Sunrise Medical |
| Location | Somerset, PA, US |
| Contact | STEPHEN KREPELKA |
| Website | http://www.sunrisemedical.co.uk/ |
| 510(k) history | 14 submissions · 14 cleared · 2002-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032056/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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