

K070328 BIPAP SYNCHRONY WITH AVAPSMay 8, 2007
92 days to decisionK070328 · Product code: **MNS** · AnesthesiologySource: <https://www.510kdatabase.net/k070328/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Continuous, Non-life-supporting (MNS) |
| Date received | Feb 5, 2007 |
| Decision date | May 8, 2007 |
| Days to decision | 92 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------------------------|
| Company | Respironics Inc., Sleep & Home Respiratory Group |
| Location | Murrysville, PA, US |
| Contact | ZITA A YURKO |
| 510(k) history | 21 submissions · 21 cleared · 2007-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070328/> 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