

K170378 AirLife Adult Heated Wire BiPAP/NIV CircuitSep 14, 2017
219 days to decisionK170378 · Product code: **BZE** · Anesthesiology
Source: <https://www.510kdatabase.net/k170378/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Heater, Breathing System W/wo Controller (not Humidifier Or Nebulizer (BZE) |
| Date received | Feb 7, 2017 |
| Decision date | Sep 14, 2017 |
| Days to decision | 219 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Vyair Medical |
| Location | Vernon Hills, IL, US |
| Contact | Sharon Nichols |
| 510(k) history | 2 submissions · 2 cleared · 2017-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170378/> 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 June 21, 2026