

**K153673 AirFit N20**May 2, 2016  
133 days to decisionK153673 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k153673/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received         | Dec 21, 2015                                  |
| Decision date         | May 2, 2016                                   |
| Days to decision      | 133 days                                      |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Resmed, Ltd.</b>   |
| Location       | Poway, CA, US   |
| Contact        | Kim Kuan Lee  |
| Website        | <a href="http://www.resmed.com/">http://www.resmed.com/</a> |
| 510(k) history | 103 submissions · 103 cleared · 1996-2019                   |

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153673/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026