

**K041362 RESMED HOSPITAL FULL FACE MASK**Jul 15, 2004  
56 days to decisionK041362 · Product code: **BZD** · AnesthesiologySource: <https://www.510kdatabase.net/k041362/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received         | May 20, 2004                                  |
| Decision date         | Jul 15, 2004                                  |
| Days to decision      | 56 days                                       |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041362/> 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