

**K162242 Comfort Flo Humidification System**Jan 19, 2017  
162 days to decisionK162242 · Product code: **BTT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k162242/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                            |
| Submission type       | Traditional   |
| Device classification | Humidifier, Respiratory Gas, (direct Patient Interface) (BTT) |
| Date received         | Aug 10, 2016  |
| Decision date         | Jan 19, 2017  |
| Days to decision      | 162 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Teleflexmedical, Inc.</b>            |
| Location       | Jeffrey, NH, US                         |
| Contact        | BRIAN GALL                              |
| 510(k) history | 64 submissions · 61 cleared · 1985-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162242/> 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 May 24, 2026