

**K153681 PleuraFlow System**Jan 20, 2016  
29 days to decisionK153681 · Product code: **OTK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k153681/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Wound Drain Catheter System (OTK)  |
| Date received         | Dec 22, 2015                       |
| Decision date         | Jan 20, 2016                       |
| Days to decision      | 29 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Clearflow, Inc.</b>                |
| Location       | Anaheim, CA, US                       |
| Contact        | DOV GAL                               |
| 510(k) history | 6 submissions · 6 cleared · 2015-2021 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153681/> 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 27, 2026