

**K203394 PleuraFlow System with FlowGlide**Mar 2, 2021  
104 days to decisionK203394 · Product code: **OTK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203394/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wound Drain Catheter System (OTK)
Date received	Nov 18, 2020
Decision date	Mar 2, 2021
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clearflow, Inc.</b>
Location	Anaheim, CA, US
Contact	Serrah Namini
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/k203394/> 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