

**K221541 LimFlow ARC**Aug 31, 2022  
96 days to decisionK221541 · Product code: **PDU** · Cardiovascular  
Source: <https://www.510kdatabase.net/k221541/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	May 27, 2022
Decision date	Aug 31, 2022
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>LimFlow, Inc.</b>
Location	San Jose, CA, US
Contact	Zachary Woodson
510(k) history	6 submissions · 6 cleared · 2022-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221541/> 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 14, 2026