

K251376 LimFlow ARCMay 31, 2025
29 days to decisionK251376 · Product code: **PDU** · CardiovascularSource: <https://www.510kdatabase.net/k251376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	May 2, 2025
Decision date	May 31, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	LimFlow, Inc.
Location	San Jose, CA, US
Contact	Haley Ritchie
510(k) history	6 submissions · 6 cleared · 2022-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251376/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026