FDA 510(k) Premarket Notification

K251376 LimFlow ARC

CLEARED

May 31, 2025
29 days to decision

K251376 · Product code: **PDU** · Cardiovascular
Source: 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