

**K254208 FLOWRUNNER Aspiration System**Mar 20, 2026  
81 days to decisionK254208 · Product code: **QEZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k254208/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Dec 29, 2025
Decision date	Mar 20, 2026
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Expanse Medical, Inc.</b>
Location	Pleasanton, CA, US
Contact	Shiva Ardakani
Website	<a href="https://www.expansemedical.com">https://www.expansemedical.com</a>
510(k) history	3 submissions · 3 cleared · 2024-2026

Expanse Medical, Inc. is an engineering-first venture studio that designs and develops regulated medical devices. The company operates with facilities in the San Francisco Bay Area and Providence, Rhode Island, with an FDA registered manufacturing facility in Pleasanton, California. Expanse transforms clinical insights into market-ready devices through first-principles engineering and disciplined execution. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on Cardiovascular devices. First clearance occurred in 2024, with t...