

K234073 ICE Aspiration SystemApr 19, 2024
119 days to decisionK234073 · Product code: **QEW** · Cardiovascular
Source: <https://www.510kdatabase.net/k234073/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Dec 22, 2023
Decision date	Apr 19, 2024
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Expanse Medical, Inc.
Location	Pleasanton, CA, US
Contact	Shiva Ardakani
Website	https://www.expansemedical.com
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...