

**K250088 FlowTrievery2 Catheter**Mar 13, 2025  
58 days to decisionK250088 · Product code: **QEW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250088/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Jan 14, 2025
Decision date	Mar 13, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inari Medical, Inc.</b>
Location	Aliso Viejo, CA, US
Contact	Rayee Patil
510(k) history	30 submissions · 30 cleared · 2015-2025

**CLINICAL EVIDENCE - NCT05560763**

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**FlowTrievery2 Pulmonary Embolectomy Clinical Study**

Status	Completed
Enrollment	50 patients (actual)
Study sites	7 sites
Condition studied	Pulmonary Embolism
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Sep 9, 2024
Sponsor	Inari Medical (Industry)

**Primary outcome**

Primary Safety Endpoint (Composite): Incidence of Adjudicated Serious Adverse Events (SAE)

**Secondary outcome**

Secondary Safety Endpoint: Number of Patient Mortalities

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05560763](https://clinicaltrials.gov/study/NCT05560763)