

K193462 ClotTrierer Thrombectomy SystemSep 9, 2020
268 days to decisionK193462 · Product code: **QEW** · Cardiovascular
Source: <https://www.510kdatabase.net/k193462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Dec 16, 2019
Decision date	Sep 9, 2020
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Inari Medical
Location	Irvine, CA, US
Contact	Eben Gordon
510(k) history	26 submissions · 26 cleared · 2015-2025

CLINICAL EVIDENCE - NCT03575364

ClotTrierer Outcomes (CLOUT) Registry

Status	Completed
Enrollment	499 patients (actual)
Study sites	43 sites
Condition studied	Deep Vein Thrombosis Leg; DVT; Chronic DVT of Lower Extremity; Acute DVT of Lower Extremity
Study type	Observational
Completion date	Jul 2, 2024
Sponsor	Inari Medical (Industry)

Primary outcome

Primary Safety Endpoint: Proportion Participants With Major Adverse Events

Secondary outcome

Primary Effectiveness Endpoint (Primary Effectiveness Cohort): Participants With Complete or Near Complete (?75%) Removal of Venous Thrombus

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03575364

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