FDA 510(k) Premarket Notification

CLEARED

K210190 ClotTriever Thrombectomy System

Feb 23, 2021
29 days to decision

K210190 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k210190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Jan 25, 2021
Decision date	Feb 23, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Irani Medical, Inc.**
Location	Irvine, CA, US
Contact	Larry Boucher
510(k) history	1 submissions · 1 cleared · 2021-2021

CLINICAL EVIDENCE - NCT03575364

ClotTriever 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