

K243549 JETi Hydrodynamic Thrombectomy SystemApr 4, 2025
140 days to decisionK243549 · Product code: **QEZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k243549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Nov 15, 2024
Decision date	Apr 4, 2025
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Medical
Location	S,Mta Clara, CA, US
Contact	Fiona Pu
Website	https://www.abbott.com
510(k) history	57 submissions · 57 cleared · 2019-2026

Abbott Medical is a global healthcare technology company headquartered in Santa Clara, US. The company specializes in life-changing medical devices and diagnostic solutions across multiple therapeutic areas. Abbott Medical maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. The company's primary focus is Cardiovascular devices, which represent 94% of its submission portfolio. Clearances span from 2019 to 2026, with recent activity demonstrating continued innovation in interventional cardiology and electrophysiology systems. R...

CLINICAL EVIDENCE - NCT04370691**JETi Lower Extremity Arterial Thrombosis**

Status	Completed
Enrollment	129 patients (actual)
Study sites	30 sites
Condition studied	Arterial Thrombosis
Study type	Observational
Completion date	Oct 9, 2024
Sponsor	Abbott Medical Devices (Industry)

Primary outcome

Primary Effectiveness Endpoint - Clot Removal Grade From Pre-JETi to Post-JETi - Core Lab Assessed - Per Vessel Analysis

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04370691