

K252315 Santreva™-ATK Endovascular Revascularization Catheter

Sep 22, 2025
59 days to decision

K252315 · Product code: **PDU** · Cardiovascular
Source: <https://www.510kdatabase.net/k252315/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Jul 25, 2025
Decision date	Sep 22, 2025
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	AngioSafe, Inc.
Location	San Jose, CA, US
Contact	Rebecca Spelich
510(k) history	1 submissions · 1 cleared · 2025-2025

CLINICAL EVIDENCE - NCT04663867

AngioSafe Peripheral CTO Crossing System Study (RESTOR-1 Study)

Status	Completed
Enrollment	79 patients (actual)
Study sites	18 sites
Condition studied	Peripheral Artery Occlusion; Peripheral Arterial Disease
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 15, 2023
Sponsor	AngioSafe, Inc. (Industry)

Primary outcome

Clinical Success of AngioSafe Peripheral CTO Crossing System

Secondary outcome

Technical Success of AngioSafe Peripheral CTO Crossing System

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04663867