

K241507 ALN Optional Vena Cava Filter (FB.010500, FF.010995, FJ.120096, FB.HOOK, FF.HOOK, FJ.HOOK)Jun 26, 2024
29 days to decisionK241507 · Product code: DTK · Cardiovascular
Source: <https://www.510kdatabase.net/k241507/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Intravascular, Cardiovascular (DTK)
Date received	May 28, 2024
Decision date	Jun 26, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	AIn S.A.R.L.
Location	Bormes Les Mimosas, FR
Contact	Nigon Alain
510(k) history	1 submissions · 1 cleared · 2024-2024

CLINICAL EVIDENCE - NCT02381509**Predicting the Safety and Effectiveness of Inferior Vena Cava Filters**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	1428 patients (actual)
Study sites	53 sites
Condition studied	Pulmonary Embolism; Deep Vein Thrombosis
Study type	Observational
Completion date	Sep 20, 2021
Sponsor	Carelon Research (Other)

Primary outcome

Composite safety endpoint of freedom from clinically significant perforation after successful filter placement, filter embolization, caval thrombotic occlusion, deep vein thrombosis, and perioperative serious adverse event

Secondary outcome**Mechanical Stability**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02381509