FDA 510(k) Premarket Notification

K240578 VenaTech® LP Vena Cava Filter System and VenaTech® Convertible Vena Cava Filter System

CLEARED

Jul 31, 2024
152 days to decision

K240578 · Product code: **DTK** · Cardiovascular
Source: https://www.510kdatabase.net/k240578/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Intravascular, Cardiovascular (DTK)
Date received	Mar 1, 2024
Decision date	Jul 31, 2024
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**B.Braun Medical, Inc.**
Location	Plymouth, MN, US
Contact	Tracy Larish
Website	http://www.bbraunusa.com/
510(k) history	148 submissions · 145 cleared · 1993-2025

B.Braun Medical, Inc. is a leading medical technology company specializing in infusion therapy, vascular access, and hospital-based medical devices. The company operates with a manufacturing facility in Plymouth, Massachusetts. B.Braun Medical has maintained a strong FDA 510(k) regulatory record since 1993. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2025 demonstrate continued innovation in infusion pumps, IV catheters, and administration sets for general hospital use. The company's cleared device portfolio focuses on smart ...

CLINICAL EVIDENCE - NCT02381509

Predicting the Safety and Effectiveness of Inferior Vena Cava Filters

Status	Completed - *No results published to ClinicalTrials.gov*
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