

K945396 FLUORO-TIP(R) HEMOSTASIS VALVE INTRODUCER SETMar 13, 1995
130 days to decisionK945396 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k945396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 3, 1994
Decision date	Mar 13, 1995
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	B.Braun Medical, Inc.
Location	Plymouth, MN, US
Contact	BARBARA ATZENHOEFER
Website	http://www.bbraunusa.com/
510(k) history	149 submissions · 146 cleared · 1993-2026

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 ...

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