

**K954123 LOW PROFILE SAFSITE Y-SITE**Nov 21, 1995  
81 days to decisionK954123 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k954123/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 1, 1995
Decision date	Nov 21, 1995
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>B.Braun Medical, Inc.</b>
Location	Plymouth, MN, US
Contact	MARK S ALSBERGE
Website	<a href="http://www.bbraunusa.com/">http://www.bbraunusa.com/</a>
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 ...