

**K142036 INFUSOMAT SPACE VOLUMETRIC INFUSION PUMP  
ADMINISTRATION SETS**Aug 25, 2014  
28 days to decisionK142036 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k142036/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jul 28, 2014
Decision date	Aug 25, 2014
Days to decision	28 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	TRACY MADDOCK
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 ...

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