

**K003029 INFUSOMAT P**Dec 4, 2000  
67 days to decisionK003029 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k003029/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Sep 28, 2000
Decision date	Dec 4, 2000
Days to decision	67 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	GARY A GULTAS
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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