

**K092313 PERFUSOR SPACE INFUSION SYRINGE PUMP SYSTEM**Nov 4, 2009  
97 days to decisionK092313 · Product code: **MEA** · General Hospital  
Source: <https://www.510kdatabase.net/k092313/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Pca (MEA)
Date received	Jul 30, 2009
Decision date	Nov 4, 2009
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>B.Braun Medical, Inc.</b>
Location	Plymouth, MN, US
Contact	SUSAN OLINGER
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 ...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k092313/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 22, 2026