

**K034066 B.BRAUN PREMIXED DIALYSATE**Mar 3, 2004  
63 days to decisionK034066 · Product code: **KPO** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k034066/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Dec 31, 2003
Decision date	Mar 3, 2004
Days to decision	63 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	PATRICIA D WILSON
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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