

**K780353 DRI-LYTE**Apr 5, 1978  
33 days to decisionK780353 · Product code: **KPO** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k780353/>**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	Mar 3, 1978
Decision date	Apr 5, 1978
Days to decision	33 days
Third-party review	No

**APPLICANT**

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Company	<b>Mallinckrodt Critical Care</b>
Location	Mchenry, IL, US
Website	<a href="https://www.mallinckrodt.com">https://www.mallinckrodt.com</a>
510(k) history	92 submissions · 92 cleared · 1976-1989

Mallinckrodt Critical Care is a medical device manufacturer based in McHenry, US. Now part of Mallinckrodt plc following a 2025 merger and subsequent restructuring, the company maintains a significant historical regulatory record in critical care and specialty medical devices. The company received FDA 510(k) clearances from total submissions between 1976 and 1989. Device clearances span anesthesiology, cardiovascular, gastroenterology, and general hospital categories. Notable cleared products include tracheal tubes, temperature monitoring systems, catheters, and related c...

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