

**K922005 GRANULYTE DIALYSATE CONCENTRATE**Mar 30, 1994  
700 days to decisionK922005 · Product code: **KPO** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k922005/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Apr 29, 1992
Decision date	Mar 30, 1994
Days to decision	700 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Fresenius USA, Inc.</b>
Location	Walker, MI, US
Contact	SCOTT N WALKER
510(k) history	38 submissions · 37 cleared · 1984-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922005/> 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 May 25, 2026