

**K911459 GRANULYTE POWDER DIALYSATE CONCENTRATE
AND MIXING**Jul 17, 1991
105 days to decisionK911459 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k911459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Apr 3, 1991
Decision date	Jul 17, 1991
Days to decision	105 days
Third-party review	No

APPLICANT

Company	Fresenius USA, Inc.
Location	Walker, MI, US
Contact	TOM FOLDEN
510(k) history	38 submissions · 37 cleared · 1984-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911459/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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