

K921134 FRESENIUS POLYSULFONE DIALYZERSDec 2, 1993
632 days to decisionK921134 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k921134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 10, 1992
Decision date	Dec 2, 1993
Days to decision	632 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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