

**K930181 BIOPURE DIALYSATE CONCENTRATE MIX
SYST/CONCENTRATE**

Nov 29, 1995
1049 days to decision

K930181 · Product code: **FKP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k930181/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Single Patient (FKP)
Date received	Jan 14, 1993
Decision date	Nov 29, 1995
Days to decision	1049 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k930181/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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