

K921456 FRESENIUS 3008/FDS-08 DIALYSATE DELIVERY SYSTEMApr 20, 1994
754 days to decisionK921456 · Product code: **FKP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k921456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Single Patient (FKP)
Date received	Mar 27, 1992
Decision date	Apr 20, 1994
Days to decision	754 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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