

**K955423 PACK H HEMODIALYSIS UREA KINETIC MODELING
SOFTWARE PROGRAM**Jun 13, 1996
198 days to decisionK955423 · Product code: **FKP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k955423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Single Patient (FKP)
Date received	Nov 28, 1995
Decision date	Jun 13, 1996
Days to decision	198 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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