FDA 510(k) Premarket Notification

K922005 GRANULYTE DIALYSATE CONCENTRATE

CLEARED

Mar 30, 1994
700 days to decision

K922005 · Product code: **KPO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k922005/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Apr 29, 1992
Decision date	Mar 30, 1994
Days to decision	700 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