FDA 510(k) Premarket Notification

K012328 HEMO-LYTE HEMODIALYSIS GRADE SODIUM BICARBONATE POWDER

CLEARED

Jan 18, 2002
179 days to decision

K012328 · Product code: **KPO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k012328/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Jul 23, 2001
Decision date	Jan 18, 2002
Days to decision	179 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Di-Chem, Inc.**
Location	Mchenry, IL, US
Contact	KEITH A BUCHHOLZ
510(k) history	6 submissions · 6 cleared · 1982-2022