FDA 510(k) Premarket Notification

K013448 PRISMASATE

CLEARED

Jan 15, 2002
90 days to decision

K013448 · Product code: **KPO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k013448/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Oct 17, 2001
Decision date	Jan 15, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gambro Renal Products**
Location	Lakewood, CO, US
Contact	FEI LAW
510(k) history	24 submissions · 23 cleared · 2000-2012