FDA 510(k) Premarket Notification

K041005 GAMBRO PRISMAFLEX AND GAMBRO PRISMAFLEX M60 & M100 SETS

CLEARED

Oct 7, 2004
171 days to decision

K041005 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k041005/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 19, 2004
Decision date	Oct 7, 2004
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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