K072232 GAMBRO POLYFLUX HEMODIALYZER, MODEL: HD-C4 SMALL

CLEARED

Sep 7, 2007
28 days to decision

K072232 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k072232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 10, 2007
Decision date	Sep 7, 2007
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gambro Renal Products, Inc.**
Location	Lakewood, CO, US
Contact	KAE MILLER
510(k) history	13 submissions · 13 cleared · 2004-2014