FDA 510(k) Premarket Notification

K080519 PRISMAFLEX M150 SET

CLEARED

Jun 13, 2008
109 days to decision

K080519 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k080519/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 25, 2008
Decision date	Jun 13, 2008
Days to decision	109 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