

K032431 PRISMA M60/M100 SETSSep 15, 2003
40 days to decisionK032431 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k032431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 6, 2003
Decision date	Sep 15, 2003
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro, Inc.
Location	Mchenry, IL, US
Contact	ROD J RYLANDS
510(k) history	86 submissions · 86 cleared · 1976-2009

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