

K023615 GAMBRO POLYFLUX 6 LR, 8 LR AND 10 LRMay 6, 2003
190 days to decisionK023615 · Product code: **MSF** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialyzer, Re-use, High Flux (MSF)
Date received	Oct 28, 2002
Decision date	May 6, 2003
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro Renal Products
Location	Lakewood, CO, US
Contact	JEFFREY R SHIDEMAN
510(k) history	24 submissions · 23 cleared · 2000-2012

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