

**K994390 GAMBRO POLYFLUX 17R, CAPILLARY DIALYZER/
FILTER**Oct 26, 2000
303 days to decisionK994390 · Product code: **MSF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k994390/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialyzer, Re-use, High Flux (MSF)
Date received	Dec 28, 1999
Decision date	Oct 26, 2000
Days to decision	303 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro Healthcare
Location	Oklahoma City, OK, US
Contact	JEFFREY R SHIDEMAN
510(k) history	13 submissions · 13 cleared · 1996-2000

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