

K770858 DIALYZER, ULTRADIFFUSER, DISPOSABLEJun 14, 1977
36 days to decisionK770858 · Product code: **FJG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k770858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Parallel Flow (FJG)
Date received	May 9, 1977
Decision date	Jun 14, 1977
Days to decision	36 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k770858/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 23, 2026