

K801045 GF120H DIALYZERJun 30, 1980
56 days to decisionK801045 · Product code: **FJI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k801045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	May 5, 1980
Decision date	Jun 30, 1980
Days to decision	56 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k801045/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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