FDA 510(k) Premarket Notification

K800336 GAMBRO LUNDIA FIBER

CLEARED

May 2, 1980
77 days to decision

K800336 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k800336/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Feb 15, 1980
Decision date	May 2, 1980
Days to decision	77 days
Third-party review	No

APPLICANT

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