FDA 510(k) Premarket Notification

K801178 COBE HF80, CAT. #18-580

CLEARED

Jul 28, 1980
70 days to decision

K801178 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k801178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	May 19, 1980
Decision date	Jul 28, 1980
Days to decision	70 days
Third-party review	No

APPLICANT

Company	**Cobe Laboratories, Inc.**
Location	Mchenry, IL, US
Website	https://www.gambro.com
510(k) history	77 submissions · 77 cleared · 1976-1993

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k801178/ 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 26, 2026