

K904566 NEW COBE CENTRYSYSTEM(TM) 100 HG DIALYZERDec 12, 1990
64 days to decisionK904566 · Product code: **FJI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k904566/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Oct 9, 1990
Decision date	Dec 12, 1990
Days to decision	64 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904566/> 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