

K944436 COBE CENTRYSYSTEM CS 200 DIALYZERJan 29, 1996
504 days to decisionK944436 · Product code: **FJI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k944436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Sep 12, 1994
Decision date	Jan 29, 1996
Days to decision	504 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cobe Renal Care, Inc.
Location	Lakewood, CO, US
Contact	JEFFREY R SHIDEMAN
510(k) history	14 submissions · 14 cleared · 1994-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944436/> 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 June 30, 2026