

**K970253 COBE CENTRYSYSTEM 3 DIALYSIS CONTROL
UNIT/COBE CARTRIDGE BLOOD TUBING SET**Sep 26, 1997
247 days to decisionK970253 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970253/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jan 22, 1997
Decision date	Sep 26, 1997
Days to decision	247 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gambro Healthcare
Location	Oklahoma City, OK, US
Contact	BENITA BOURQUE,, RAC
510(k) history	13 submissions · 13 cleared · 1996-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970253/> 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 29, 2026