

K954623 REDY 2000 SYSTEM (THERAPEUTIC PLASMA EXCHANGE OPTION AND MONITORING LINE Y-CONNECTOR)Aug 28, 1996
328 days to decisionK954623 · Product code: FKT · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k954623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Sorbent Regenerated (FKT)
Date received	Oct 5, 1995
Decision date	Aug 28, 1996
Days to decision	328 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gambro Healthcare
Location	Oklahoma City, OK, US
Contact	MATHEW M HULL
510(k) history	13 submissions · 13 cleared · 1996-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954623/> 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