

K954987 ALTRATOUCH 1000 HEMODIALYSIS DELIVERY SYSTEMAug 8, 1996
282 days to decisionK954987 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k954987/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 31, 1995
Decision date	Aug 8, 1996
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Althin Medical AB an Affiliate of Baxter Intl
Location	Miami Lakes, FL, US
Contact	ALAN LEWIS
510(k) history	27 submissions · 27 cleared · 1991-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954987/> 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