

K945595 ALTREX(R) 200 HEMODIALYZERMar 8, 1995
114 days to decisionK945595 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k945595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 14, 1994
Decision date	Mar 8, 1995
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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