

K945624 MCA(TM) 160 HEMODIALYZERMay 18, 1995
184 days to decisionK945624 · Product code: **FJI** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Nov 15, 1994
Decision date	May 18, 1995
Days to decision	184 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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