

K945631 155 SCE(TM) HEMODIALYZERMay 18, 1995
183 days to decisionK945631 · 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 16, 1994
Decision date	May 18, 1995
Days to decision	183 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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