

**K962309 ALTERNATE ENCAPSULATING RESIN SYSTEM FOR
MCA HEMODIALYZERS**Dec 27, 1996
193 days to decisionK962309 · Product code: **FJI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k962309/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Jun 17, 1996
Decision date	Dec 27, 1996
Days to decision	193 days
Third-party review	No
Summary / Statement	Statement

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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