

**K990643 PS 15 POLYSULFONE HOLLOW FIBER MEMBRANE
HEMODIALYZER, MODEL 239-015**Dec 7, 1999
284 days to decisionK990643 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k990643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 26, 1999
Decision date	Dec 7, 1999
Days to decision	284 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990643/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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