

**K992566 AF-150 HEMODIALYZER**Jan 18, 2000  
169 days to decisionK992566 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k992566/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 2, 1999
Decision date	Jan 18, 2000
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Althin Medical AB</b>
Location	372 21 Ronneby, SE
Contact	LARS-OLOF SANDBERG
510(k) history	7 submissions · 7 cleared · 1999-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992566/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 1, 2026