

**K913950 DUO-FLUX(R) ULTRA HIGH PERFORM ARTIFICIAL KIDNEY**Nov 1, 1991  
58 days to decisionK913950 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k913950/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Sep 4, 1991
Decision date	Nov 1, 1991
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Althin Medical AB an Affiliate of Baxter Intl</b>
Location	Miami Lakes, FL, US
Contact	MARIAN D HARDING
510(k) history	27 submissions · 27 cleared · 1991-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913950/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026