K913950 DUO-FLUX(R) ULTRA HIGH PERFORM ARTIFICIAL KIDNEY

CLEARED

Nov 1, 1991
58 days to decision

K913950 · 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	**Althin Medical AB an Affiliate of Baxter Intl**
Location	Miami Lakes, FL, US
Contact	MARIAN D HARDING
510(k) history	27 submissions · 27 cleared · 1991-1999