FDA 510(k) Premarket Notification

K954987 ALTRATOUCH 1000 HEMODIALYSIS DELIVERY SYSTEM

CLEARED

Aug 8, 1996
282 days to decision

K954987 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k954987/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 31, 1995
Decision date	Aug 8, 1996
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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