FDA 510(k) Premarket Notification

K992566 AF-150 HEMODIALYZER

CLEARED

Jan 18, 2000
169 days to decision

K992566 · 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	**Althin Medical AB**
Location	372 21 Ronneby, SE
Contact	LARS-OLOF SANDBERG
510(k) history	7 submissions · 7 cleared · 1999-2000