FDA 510(k) Premarket Notification

K853510 MINIFILTER HEMOFILTER

CLEARED

Sep 12, 1985
22 days to decision

K853510 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k853510/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 21, 1985
Decision date	Sep 12, 1985
Days to decision	22 days
Third-party review	No

APPLICANT

Company	**Amicon, Inc.**
Location	Mchenry, IL, US
Contact	JAMES M DELANCY
510(k) history	20 submissions · 20 cleared · 1976-1993