FDA 510(k) Premarket Notification

K895405 AMICON MINIFILTER PLUS HEMOFILTER

CLEARED

Jan 11, 1990
126 days to decision

K895405 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k895405/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Sep 7, 1989
Decision date	Jan 11, 1990
Days to decision	126 days
Third-party review	No

APPLICANT

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