FDA 510(k) Premarket Notification

CLEARED

K873887 MODIFIED HOLLOW FIBERS USED IN DIAFILTER HEMOFIL.

Dec 9, 1987
77 days to decision

K873887 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k873887/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Sep 23, 1987
Decision date	Dec 9, 1987
Days to decision	77 days
Third-party review	No

APPLICANT

Company	**W.R. Grace & Co.-Conn.**
Location	Lexington, MA, US
Contact	JAMES M DELANEY
510(k) history	2 submissions · 2 cleared · 1986-1987