FDA 510(k) Premarket Notification

CLEARED

K892262 FRESENIUS HEMOFLOW, F40M, F50M, F60M & F80M

Apr 25, 1989
20 days to decision

K892262 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k892262/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 5, 1989
Decision date	Apr 25, 1989
Days to decision	20 days
Third-party review	No

APPLICANT

Company	**Fresenius USA, Inc.**
Location	Walker, MI, US
Contact	SCOTT N WALKER
510(k) history	38 submissions · 37 cleared · 1984-1999