FDA 510(k) Premarket Notification

K883195 FRESENIUS F8 DIALYZER

CLEARED

Sep 13, 1988
47 days to decision

K883195 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k883195/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 28, 1988
Decision date	Sep 13, 1988
Days to decision	47 days
Third-party review	No

APPLICANT

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