FDA 510(k) Premarket Notification

CLEARED

K991520 FRESENIUS ON LINE CLEARANCE MONITOR WITH THE ADDITION OF ACCESS FLOW DETERMINATION

Jul 30, 1999
88 days to decision

K991520 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k991520/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 3, 1999
Decision date	Jul 30, 1999
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Fresenius Medical Care North America**
Location	Lexington, MA, US
Contact	ARTHUR EILINSFELD
510(k) history	43 submissions · 43 cleared · 1998-2025