CLEARED

K992275 FRESENIUS MODIFIED F400 LOW VOLUME HEMOCONCENTRATOR F3000 & MODIFIED F400 LOW VOL HEMOCONCENTRATOR W/TUBING SET F3000TS

Aug 4, 1999
28 days to decision

K992275 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k992275/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 7, 1999
Decision date	Aug 4, 1999
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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