FDA 510(k) Premarket Notification

K961465 2008H ON LINE CLEARANCE MONITOR

CLEARED

Jul 3, 1997
442 days to decision

K961465 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k961465/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 17, 1996
Decision date	Jul 3, 1997
Days to decision	442 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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