FDA 510(k) Premarket Notification

K912208 FRESENIUS SAFE-CONNECT CAPD MANUAL ASSIST DEVICE

CLEARED

Jul 24, 1991
65 days to decision

K912208 · Product code: **KDJ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k912208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, For Peritoneal Dialysis, Disposable (KDJ)
Date received	May 20, 1991
Decision date	Jul 24, 1991
Days to decision	65 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