FDA 510(k) Premarket Notification

K022913 NXSTAGE PREMIXED DIALYSATE

CLEARED

Oct 21, 2002
48 days to decision

K022913 · Product code: **KPO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k022913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Sep 3, 2002
Decision date	Oct 21, 2002
Days to decision	48 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Nxstage Medical, Inc.**
Location	Tewksburt, MA, US
Contact	NORMA LEMAY
510(k) history	51 submissions · 51 cleared · 2001-2024