FDA 510(k) Premarket Notification

K053286 MODIFICATION TO: NXSTAGE PUREFLOW-B SOLUTION

CLEARED

Dec 22, 2005
27 days to decision

K053286 · Product code: **KPO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k053286/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Nov 25, 2005
Decision date	Dec 22, 2005
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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