

K053286 MODIFICATION TO: NXSTAGE PUREFLOW-B SOLUTION

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

510k Database - www.510kdatabase.net
 Device record: <https://www.510kdatabase.net/k053286/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026