

K123395 NXSTAGE SYSTEM ONE LOW VOLUME CARTRIDGE EXPRESSMar 7, 2013
122 days to decisionK123395 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k123395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 5, 2012
Decision date	Mar 7, 2013
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nxstage Medical, Inc.
Location	Tewksburt, MA, US
Contact	MARY LOU STROUMBOS
510(k) history	51 submissions · 51 cleared · 2001-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123395/> 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