

K050525 NXSTAGE SYSTEM ONEJun 24, 2005
114 days to decisionK050525 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k050525/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 2, 2005
Decision date	Jun 24, 2005
Days to decision	114 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

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