

K122051 NXSTAGE SYSTEM ONEApr 23, 2013
285 days to decisionK122051 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k122051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 12, 2012
Decision date	Apr 23, 2013
Days to decision	285 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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