

**K041424 NXSTAGE SYSTEM ONE**Jul 2, 2004  
35 days to decisionK041424 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k041424/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 28, 2004
Decision date	Jul 2, 2004
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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