

**K140526 NXSTAGE SYSTEM ONE**May 19, 2014  
76 days to decisionK140526 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k140526/>**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	Mar 4, 2014
Decision date	May 19, 2014
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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