

**K133547 NXSTAGE SYSTEM ONE WITH NXVIEW**Mar 3, 2014  
104 days to decisionK133547 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k133547/>**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	Nov 19, 2013
Decision date	Mar 3, 2014
Days to decision	104 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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