

**K141752 NXSTAGE SYSTEM ONE**Dec 19, 2014  
172 days to decisionK141752 · Product code: **ODN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k141752/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ultrafiltration-controlled Nocturnal Dialysate Delivery System (ODN)
Date received	Jun 30, 2014
Decision date	Dec 19, 2014
Days to decision	172 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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