

K150472 NxStage System OneJun 4, 2015
101 days to decisionK150472 · Product code: **ODN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k150472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ultrafiltration-controlled Nocturnal Dialysate Delivery System (ODN)
Date received	Feb 23, 2015
Decision date	Jun 4, 2015
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nxstage Medical, Inc.
Location	Tewksburt, MA, US
Contact	Mary Lou Stroumbos
510(k) history	51 submissions · 51 cleared · 2001-2024

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