

K171331 NxStage System OneAug 24, 2017
108 days to decisionK171331 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k171331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 8, 2017
Decision date	Aug 24, 2017
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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