

K181991 NxStage Connected Health SystemSep 26, 2018
62 days to decisionK181991 · Product code: **FKP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k181991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Single Patient (FKP)
Date received	Jul 26, 2018
Decision date	Sep 26, 2018
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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