

K183158 NxStage Cartridge Express with SpeedswapAug 9, 2019
267 days to decisionK183158 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k183158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 15, 2018
Decision date	Aug 9, 2019
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	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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