

**K232803 NxStage System One with Cartridge Express  
(CAR-170-E and CAR-172-E)**Mar 14, 2024  
184 days to decisionK232803 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k232803/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Sep 12, 2023
Decision date	Mar 14, 2024
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nxstage Medical, Inc.</b>
Location	Tewksburt, MA, US
Contact	Denise Oppermann
510(k) history	51 submissions · 51 cleared · 2001-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232803/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026