

**K143313 NxStage Therapeutic Plasma Exchange (TPE)
Cartridge**Mar 20, 2015
121 days to decisionK143313 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k143313/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 19, 2014
Decision date	Mar 20, 2015
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143313/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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