

**K093069 NXSTAGE SYSTEM ONE WITH THERAPEUTIC
PLASMA EXCHANGE CARTRIDGE**Oct 23, 2010
388 days to decisionK093069 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k093069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Sep 30, 2009
Decision date	Oct 23, 2010
Days to decision	388 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093069/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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