

K113023 STREAMLINE AIRLESS SYSTEM SET WITH PRE-ATTACHED DIALYZERDec 21, 2012
437 days to decisionK113023 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k113023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 11, 2011
Decision date	Dec 21, 2012
Days to decision	437 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113023/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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