FDA 510(k) Premarket Notification

CLEARED

K123395 NXSTAGE SYSTEM ONE LOW VOLUME CARTRIDGE EXPRESS

Mar 7, 2013
122 days to decision

K123395 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k123395/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 5, 2012
Decision date	Mar 7, 2013
Days to decision	122 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