

K153384 Low Potassium Dextran Solution with Tris DiluentFeb 19, 2016
88 days to decisionK153384 · Product code: **KDN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k153384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	Nov 23, 2015
Decision date	Feb 19, 2016
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	United Therapeutics Corporation
Location	Research Triangle Park, NC, US
Contact	Rita Lee
510(k) history	1 submissions · 1 cleared · 2016-2016

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