

K050827 NORMOCARD 25 (STERILE BICARBONATE RENAL DIALYSIS CONCENTRATE)

Aug 22, 2005
143 days to decision

K050827 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k050827/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Apr 1, 2005
Decision date	Aug 22, 2005
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dialysis Solutions, Inc.
Location	Lincolnshire, IL, US
Contact	MARCY MACDONALD
510(k) history	1 submissions · 1 cleared · 2005-2005

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Device record: <https://www.510kdatabase.net/k050827/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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