

K131611 FRESENIUS DRY ACID DISSOLUTION UNITSAug 29, 2013
87 days to decisionK131611 · Product code: **KPO** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k131611/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Jun 3, 2013
Decision date	Aug 29, 2013
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fresenius Medical Care North America
Location	Lexington, MA, US
Contact	DENISE OPPERMANN
510(k) history	43 submissions · 43 cleared · 1998-2025

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