

K120005 ACDSMar 29, 2012
86 days to decisionK120005 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k120005/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Jan 3, 2012
Decision date	Mar 29, 2012
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Isopure, Corp.
Location	Simpsonville, KY, US
Contact	KEVIN GILLESPIE
510(k) history	5 submissions · 5 cleared · 2000-2020

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