

K180679 CitriCon Liquid and Powder (Acid Concentrate acidified with Citric Acid), AcetiCon Liquid and Powder (Acid Concentrate acidified with Acetic Acid or Na Di Acetate), BicarboCon Liquid and Powder (Bicarb Concentrate), RenaCon Liquid and Powder (Acetate Concentrate with Na Acetate)Dec 7, 2018
267 days to decisionK180679 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Mar 15, 2018
Decision date	Dec 7, 2018
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Global Scientific Technologies, LLC
Location	Greer, SC, US
Contact	William J. Griswold, Jr.
510(k) history	1 submissions · 1 cleared · 2018-2018

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