FDA 510(k) Premarket Notification

K191093 Isopure Dry Acid Dissolution System

CLEARED

Jan 22, 2020
272 days to decision

K191093 · Product code: **KPO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k191093/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Apr 25, 2019
Decision date	Jan 22, 2020
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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