FDA 510(k) Premarket Notification

# K171015 Citryte

**CLEARED**

Oct 13, 2017
192 days to decision

K171015 · Product code: **KPO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k171015/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO) |
| Date received | Apr 4, 2017 |
| Decision date | Oct 13, 2017 |
| Days to decision | 192 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Di-Chem, Inc.** |
| Location | Mchenry, IL, US |
| Contact | Keith Buchholz |
| 510(k) history | 6 submissions · 6 cleared · 1982-2022 |