FDA 510(k) Premarket Notification

K801385 K1 POTASSIUM ACETATE ADDITIVE

CLEARED

Jul 21, 1980
38 days to decision

K801385 · Product code: **FKT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k801385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Sorbent Regenerated (FKT)
Date received	Jun 13, 1980
Decision date	Jul 21, 1980
Days to decision	38 days
Third-party review	No

APPLICANT

Company	**Organon Teknika Corp.**
Location	Mchenry, IL, US
510(k) history	130 submissions · 129 cleared · 1980-2000