

K810925 NATURALYTE BICARBONATE DIALYSATE CONCEN.Apr 23, 1981
17 days to decisionK810925 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k810925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Apr 6, 1981
Decision date	Apr 23, 1981
Days to decision	17 days
Third-party review	No

APPLICANT

Company	Erika, Inc.
Location	Mchenry, IL, US
Website	https://www.erika.com
510(k) history	43 submissions · 43 cleared · 1976-1985

Erika, Inc. is a medical device company based in McHenry, US. The company specialized in Gastroenterology & Urology devices. Erika, Inc. received FDA 510(k) clearances from total submissions between 1976 and 1985. The company's regulatory focus centered on Gastroenterology & Urology devices, which represented 86% of its submission portfolio. Notable cleared products included infusion pump administration sets, artificial kidney filtration systems, and bicarbonate concentrate formulations. This company is inactive and represents a historical regulatory record. No FDA 510(k)...
