FDA 510(k) Premarket Notification

K821304 CENTRALYTE BICARBONATE CONCENTRATE

CLEARED

May 18, 1982
14 days to decision

K821304 · Product code: **KPO** · Hematology
Source: https://www.510kdatabase.net/k821304/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	May 4, 1982
Decision date	May 18, 1982
Days to decision	14 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)...