FDA 510(k) Premarket Notification

K850866 TORAY INDUSTRIES FILTRYZER HOLLOW FIBER KIDNEY B1L

CLEARED

Apr 3, 1985
33 days to decision

K850866 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k850866/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 1, 1985
Decision date	Apr 3, 1985
Days to decision	33 days
Third-party review	No

APPLICANT

Company	**Erika, Inc.**
Location	Mchenry, IL, US
Contact	DEL DONNA
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)...