FDA 510(k) Premarket Notification

K822485 HPF 100,200,300 CAPILLARY FLOW DIALYZ

CLEARED

Aug 30, 1982
13 days to decision

K822485 · Product code: **FKQ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k822485/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Central Multiple Patient (FKQ)
Date received	Aug 17, 1982
Decision date	Aug 30, 1982
Days to decision	13 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)...