

K771349 MODIFICATION TO KIDNEY DIALYZERAug 2, 1977
12 days to decisionK771349 · Product code: **FHS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k771349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Single Coil (FHS)
Date received	Jul 21, 1977
Decision date	Aug 2, 1977
Days to decision	12 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)...
