FDA 510(k) Premarket Notification

K760374 DIALYZER (MODEL 1850)

CLEARED

Oct 27, 1976
83 days to decision

K760374 · Product code: **FHS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k760374/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Single Coil (FHS)
Date received	Aug 5, 1976
Decision date	Oct 27, 1976
Days to decision	83 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)...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k760374/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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