FDA 510(k) Premarket Notification

K831175 FILTRYZER HOLLOW FIBER ARTIF. KIDNEY

CLEARED

Jun 22, 1984
438 days to decision

K831175 · Product code: **KOC** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k831175/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Blood Circuit, Hemodialysis (KOC)
Date received	Apr 11, 1983
Decision date	Jun 22, 1984
Days to decision	438 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)...