FDA 510(k) Premarket Notification

K840859 MAKS CENTRAL DELIVERY SYS-11-200 ETC

CLEARED

May 22, 1984
88 days to decision

K840859 · Product code: **KOC** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k840859/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Blood Circuit, Hemodialysis (KOC)
Date received	Feb 24, 1984
Decision date	May 22, 1984
Days to decision	88 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)...