

**K770382 NEEDLE, FISTULA, ERIKA**Mar 8, 1977  
8 days to decisionK770382 · Product code: **KOC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k770382/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Blood Circuit, Hemodialysis (KOC)
Date received	Feb 28, 1977
Decision date	Mar 8, 1977
Days to decision	8 days
Third-party review	No

**APPLICANT**

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Company	<b>Erika, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.erika.com">https://www.erika.com</a>
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)...

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