

**K812811 MICROCOIL 80 DIALYZER**Dec 3, 1981  
58 days to decisionK812811 · Product code: **FHS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k812811/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Single Coil (FHS)
Date received	Oct 6, 1981
Decision date	Dec 3, 1981
Days to decision	58 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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