

K822361 DIANEAL SOLUTION EXCHANGE DEVICE #5C4193Aug 16, 1982
10 days to decisionK822361 · Product code: **FKX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k822361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Peritoneal, Automatic Delivery (FKX)
Date received	Aug 6, 1982
Decision date	Aug 16, 1982
Days to decision	10 days
Third-party review	No

APPLICANT

Company	Travenol Laboratories, S.A.
Location	Mchenry, IL, US
Website	https://www.baxter.com
510(k) history	206 submissions · 206 cleared · 1976-1988

Travenol Laboratories, S.A. is a medical device manufacturer based in McHenry, US. The company specializes in infusion, dialysis, and hospital care devices. Travenol Laboratories received FDA 510(k) clearances from total submissions between 1976 and 1988. The company's cleared devices span general hospital and gastroenterology/urology categories, including infusion systems, dialysis equipment, and administration sets. This regulatory record reflects the company's historical focus on critical care and renal therapy technologies. The company is inactive and represents a his...

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