FDA 510(k) Premarket Notification

# K800221 CF/211 CAPILLARY FLOW DIALYZER, #5M1784

**CLEARED**

Feb 26, 1980
22 days to decision

K800221 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k800221/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialyzer, Capillary, Hollow Fiber (FJI) |
| Date received | Feb 4, 1980 |
| Decision date | Feb 26, 1980 |
| Days to decision | 22 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...