FDA 510(k) Premarket Notification

# K821950 Q-PAK URINE TOXICOLOGY CONTROL UNASSAYED

**CLEARED**

Jul 20, 1982
20 days to decision

K821950 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k821950/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drug Mixture Control Materials (DIF) |
| Date received | Jun 30, 1982 |
| Decision date | Jul 20, 1982 |
| Days to decision | 20 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...