FDA 510(k) Premarket Notification

CLEARED

K821973 Q-PAK URINE TOXICOLOGY CONTROL, UNASSAY.

Jul 20, 1982
18 days to decision

K821973 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k821973/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Jul 2, 1982
Decision date	Jul 20, 1982
Days to decision	18 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...