FDA 510(k) Premarket Notification

K771375 PRESSURE MODULE 5M1247

CLEARED

Sep 15, 1977
52 days to decision

K771375 · Product code: **FKQ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k771375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Central Multiple Patient (FKQ)
Date received	Jul 25, 1977
Decision date	Sep 15, 1977
Days to decision	52 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...