FDA 510(k) Premarket Notification

K772318 DIALYZER STANDARD, CODE 5DM1780

CLEARED

Jan 26, 1978
38 days to decision

K772318 · Product code: **FJG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k772318/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Parallel Flow (FJG)
Date received	Dec 19, 1977
Decision date	Jan 26, 1978
Days to decision	38 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...