FDA 510(k) Premarket Notification

K850061 MICRO VOLUME DOUBLE LINE EXTENSION SET

CLEARED

Mar 27, 1985
78 days to decision

K850061 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k850061/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jan 8, 1985
Decision date	Mar 27, 1985
Days to decision	78 days
Third-party review	No

APPLICANT

Company	**Travenol Laboratories, S.A.**
Location	Mchenry, IL, US
Contact	ROGER A LEROUX
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...