FDA 510(k) Premarket Notification

K770762 BAG, URINARY, DRAINAGE, 2D9013

CLEARED

May 10, 1977
14 days to decision

K770762 · Product code: **KNX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k770762/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Urine, (and Accessories) For Indwelling Catheter (KNX)
Date received	Apr 26, 1977
Decision date	May 10, 1977
Days to decision	14 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...

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Device record: https://www.510kdatabase.net/k770762/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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