FDA 510(k) Premarket Notification

K853208 125I ESTRADIOL DIRECT RADIOIMMUNOASSAY

CLEARED

Aug 19, 1985
19 days to decision

K853208 · Product code: **CHP** · Chemistry
Source: https://www.510kdatabase.net/k853208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	Jul 31, 1985
Decision date	Aug 19, 1985
Days to decision	19 days
Third-party review	No

APPLICANT

Company	**Travenol Laboratories, S.A.**
Location	Mchenry, IL, US
Contact	ROSA L DITUCCI
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...