

K801409 GAMMADAB B-HCG RADIOIMMUNOASSAY KITJul 14, 1980
28 days to decisionK801409 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k801409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jun 16, 1980
Decision date	Jul 14, 1980
Days to decision	28 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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