FDA 510(k) Premarket Notification

K935702 DADE INNOVIN II

CLEARED

Nov 22, 1994
357 days to decision

K935702 · Product code: **GJS** · Hematology
Source: https://www.510kdatabase.net/k935702/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Nov 30, 1993
Decision date	Nov 22, 1994
Days to decision	357 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baxter Diagnostics, Inc.**
Location	Miami, FL, US
Contact	RONALD H LENTSCH, PH.D
Website	https://www.baxter.com/
510(k) history	72 submissions · 72 cleared · 1988-1995

Baxter Diagnostics, Inc. is a diagnostic device manufacturer based in Miami, US. The company specialized in microbiology and chemistry diagnostic solutions. Baxter Diagnostics received FDA 510(k) clearances from total submissions between 1988 and 1995. The company's regulatory focus centered on microbiology devices, particularly dried antimicrobial susceptibility testing panels and related diagnostic assays. This historical record reflects the company's core expertise in microbial identification and resistance testing. The company is no longer active in FDA 510(k) submiss...