FDA 510(k) Premarket Notification

K921326 DADE RECOMBOPLASTIN S

CLEARED

Jul 27, 1992
131 days to decision

K921326 · Product code: **GJS** · Hematology
Source: https://www.510kdatabase.net/k921326/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Mar 18, 1992
Decision date	Jul 27, 1992
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baxter Diagnostics, Inc.**
Location	Miami, FL, US
Contact	ALODIA M RUIZ
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 The company is no longer active in FDA 510(k) submiss...