FDA 510(k) Premarket Notification

CLEARED

K933188 DADE (PAI-1) CHROMOGENIC ASSAY DADE COAGTROL-PAI

Sep 22, 1993
84 days to decision

K933188 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k933188/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jun 30, 1993
Decision date	Sep 22, 1993
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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 The company is no longer active in FDA 510(k) submiss...