FDA 510(k) Premarket Notification

K922581 BARTELS RUBELLA IGM EIA

CLEARED

Sep 17, 1992
113 days to decision

K922581 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k922581/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	May 27, 1992
Decision date	Sep 17, 1992
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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 The company is no longer active in FDA 510(k) submiss...