FDA 510(k) Premarket Notification

K922580 BARTELS CYTOMEGALOVIRUS IGM EIA

CLEARED

Apr 8, 1993
316 days to decision

K922580 · Product code: **LKQ** · Microbiology
Source: https://www.510kdatabase.net/k922580/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibody Igm,if, Cytomegalovirus Virus (LKQ)
Date received	May 27, 1992
Decision date	Apr 8, 1993
Days to decision	316 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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 The company is no longer active in FDA 510(k) submiss...