

K941317 DRIED GRAM NEGATIVE/CEFMETAZOLEJan 31, 1995
319 days to decisionK941317 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k941317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Mar 18, 1994
Decision date	Jan 31, 1995
Days to decision	319 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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 The company is no longer active in FDA 510(k) submiss...
