

K943510 DRIED GRAM-POSITIVE MIC/COMBO PANELSDec 2, 1994
135 days to decisionK943510 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k943510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Jul 20, 1994
Decision date	Dec 2, 1994
Days to decision	135 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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 The company is no longer active in FDA 510(k) submiss...
