

**K950817 DRIED GRAM POSITIVE MIC/COMBO  
PANELS/PNEUMOCOCCI**Apr 25, 1995  
62 days to decisionK950817 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k950817/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Feb 22, 1995
Decision date	Apr 25, 1995
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Baxter Diagnostics, Inc.</b>
Location	Miami, FL, US
Contact	SHARON HANSEN
Website	<a href="https://www.baxter.com/">https://www.baxter.com/</a>
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 The company is no longer active in FDA 510(k) submiss...

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