

**K941459 GRAM POSITIVE DRIED OVERNIGHT  
PANELS/LOMEFLOX**Feb 3, 1995  
316 days to decisionK941459 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k941459/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Mar 24, 1994
Decision date	Feb 3, 1995
Days to decision	316 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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 The company is no longer active in FDA 510(k) submiss...

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Device record: <https://www.510kdatabase.net/k941459/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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