

**K935987 FLEXTRANS**Aug 15, 1994  
244 days to decisionK935987 · Product code: **JSM** · Microbiology  
Source: <https://www.510kdatabase.net/k935987/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Non-propagating Transport (JSM)
Date received	Dec 14, 1993
Decision date	Aug 15, 1994
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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 The company is no longer active in FDA 510(k) submiss...

---