

**K924074 STRATUS VITAMIN B12 FLUOROMETRIC ENZYME-LINKED**Oct 26, 1992  
75 days to decisionK924074 · Product code: **CDD** · Chemistry  
Source: <https://www.510kdatabase.net/k924074/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Aug 12, 1992
Decision date	Oct 26, 1992
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baxter Diagnostics, Inc.</b>
Location	Miami, FL, US
Contact	NANCY A HORNBAKER
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 The company is no longer active in FDA 510(k) submiss...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/k924074/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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