

**K934003 STRATUS DIGOXIN FLOUROMETRIC ENZYME
IMMUNOASSAY**Nov 22, 1994
462 days to decisionK934003 · Product code: **DKA** · Toxicology
Source: <https://www.510kdatabase.net/k934003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Digoxin (DKA)
Date received	Aug 17, 1993
Decision date	Nov 22, 1994
Days to decision	462 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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 The company is no longer active in FDA 510(k) submiss...

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