

K874274 REVISED LABELING FOR AMPHETAMINE TEST KITNov 13, 1987
24 days to decisionK874274 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k874274/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Oct 20, 1987
Decision date	Nov 13, 1987
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	ADRIENNE CHOMA
510(k) history	296 submissions · 296 cleared · 1983-1999

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Device record: <https://www.510kdatabase.net/k874274/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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