

K973075 ONTRAK TESTSTIK FOR AMPHETAMINES, ONTRAK TESTSTIK FOR COCAINE, ONTRAK TESTSTIK FOR MORPHINE, ONTRAK TESTSTIK FOR PCP, ONOct 9, 1997
52 days to decisionK973075 · Product code: **DKZ** · Toxicology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Aug 18, 1997
Decision date	Oct 9, 1997
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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