

K912758 ABUSCREEN ONLINE FOR AMPHETAMINESJul 26, 1991
35 days to decisionK912758 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k912758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jun 21, 1991
Decision date	Jul 26, 1991
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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