

**K910278 ABUSCREEN(R) ONTRAK(TM) FOR  
AMPHETAMINE(500 NG/ML)**Apr 3, 1991  
70 days to decisionK910278 · Product code: **DKZ** · Toxicology  
Source: <https://www.510kdatabase.net/k910278/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jan 23, 1991
Decision date	Apr 3, 1991
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k910278/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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