

**K981197 ONE STEP URINE DRUG OF ABUSE AMPHETAMINE TEST**Jun 16, 1998  
75 days to decisionK981197 · Product code: **DKZ** · Toxicology  
Source: <https://www.510kdatabase.net/k981197/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Apr 2, 1998
Decision date	Jun 16, 1998
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tcpi, Inc.</b>
Location	Ft. Lauderdale, FL, US
Contact	JACK L ARONOWITZ .
510(k) history	14 submissions · 14 cleared · 1992-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981197/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026