

**K050394 SURE-SCREEN AMPHETAMINE, BENZODIAZEPINE,  
COCAINE, METHAMPHETAMINE/MDMA, METHADONE,  
OPIATES, PHENCYCLIDINE & CANNABINOIDS**Oct 25, 2005  
251 days to decisionK050394 · Product code: **DKZ** · Chemistry  
Source: <https://www.510kdatabase.net/k050394/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Feb 16, 2005
Decision date	Oct 25, 2005
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtox Diagnostics, Inc.</b>
Location	Burlington, NC, US
Contact	ALAN MORRIS
510(k) history	22 submissions · 22 cleared · 1998-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050394/> 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 May 14, 2026