

**K053337 DIMENSION URINE ECSTASY SCREEN FLEX  
REAGENT CARTRIDGE, MODEL DF 109**May 19, 2006  
169 days to decisionK053337 · Product code: **DKZ** · Chemistry  
Source: <https://www.510kdatabase.net/k053337/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Dec 1, 2005
Decision date	May 19, 2006
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dade Behring, Inc.</b>
Location	Newark,, DE, US
Contact	YUK-TING LEWIS
510(k) history	343 submissions · 343 cleared · 1978-2010

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053337/>. 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 19, 2026