

**K051235 ON TRAK TESTCARD**

Jun 8, 2005  
26 days to decision

K051235 · Product code: **DKZ** · Chemistry  
Source: <https://www.510kdatabase.net/k051235/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	May 13, 2005
Decision date	Jun 8, 2005
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Varian, Inc.</b>
Location	Lake Forest, CA, US
Contact	LORNA GAMBOA
Website	<a href="http://www.varianinc.com/">http://www.varianinc.com/</a>
510(k) history	5 submissions · 5 cleared · 2004-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k051235/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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