

**K033902 ONTRAK TESTCUP II AND ONSITE CUPKIT**

Jan 20, 2004  
 34 days to decision

K033902 · Product code: **DKZ** · Toxicology  
 Source: <https://www.510kdatabase.net/k033902/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Dec 17, 2003
Decision date	Jan 20, 2004
Days to decision	34 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/k033902/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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