

**K010645 AT HOME DRUG TEST, MODEL 9063 T**Mar 30, 2001  
25 days to decisionK010645 · Product code: **DKZ** · Toxicology  
Source: <https://www.510kdatabase.net/k010645/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Mar 5, 2001
Decision date	Mar 30, 2001
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Phamatech</b>
Location	San Diego, CA, US
Contact	CARL A MONGIOVI
510(k) history	47 submissions · 47 cleared · 1996-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010645/> 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