

**K182738 Single and Multi-Drug Rapid Test Panel With Adulteration (Urine), Single and Multi-Drug Rapid Test Panel (Urine), Single and Multi-Drug Rapid Test Cup With Adulteration (Urine), Single and Multi-Drug Rapid Test Cup (Urine), Single Drug Rapid Test Dipstick (Urine), Single and Multi-Drug Home Rapid Test Panel (Urine), Single and Multi-Drug Home Rapid Test Cup (Urine), Single Drug Home Rapid Test Dipstick (Urine)**

Mar 27, 2019  
180 days to decision

K182738 · Product code: **DKZ** · Toxicology  
Source: <https://www.510kdatabase.net/k182738/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Sep 28, 2018
Decision date	Mar 27, 2019
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou AllTest Biotech Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Feng-Yu Lee
510(k) history	14 submissions · 14 cleared · 2019-2026

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

Device record: <https://www.510kdatabase.net/k182738/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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