

**K231137 Xenta Drug Screen Cup, Xenta Drug Screen Dipcard**May 19, 2023  
28 days to decisionK231137 · Product code: **DKZ** · Toxicology  
Source: <https://www.510kdatabase.net/k231137/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Apr 21, 2023
Decision date	May 19, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xenta Biomedical Science Co., Ltd.</b>
Location	Guangzhou, CN
Contact	Huang Ling
510(k) history	2 submissions · 2 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231137/> 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 May 26, 2026