

K161251 CLUNGENE Amphetamine Tests, CLUNGENE Cocaine Tests, CLUNGENE Oxazepam TestsAug 30, 2016
119 days to decisionK161251 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k161251/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	May 3, 2016
Decision date	Aug 30, 2016
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou Clongene Biotech Co., Ltd.
Location	Hangzhou, CN
Contact	Zheng Shujian
510(k) history	9 submissions · 9 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161251/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026