

K161214 Wondfo Amphetamine Urine Test AMP 500 (Cup, Dipcard), Wondfo Cocaine Urine Test COC 150(Cup, Dipcard), Wondfo Methamphetamine Urine Test MET 500 (Cup, Dipcard)Jun 27, 2016
59 days to decisionK161214 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k161214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Apr 29, 2016
Decision date	Jun 27, 2016
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Wondfo Biotech Co., Ltd.
Location	Yardley, PA, US
Contact	Bin Chen
510(k) history	43 submissions · 43 cleared · 2005-2026

REGULATORY CONSULTANT

Consulting firm	Lsi International
Contact	Joe Shia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161214/>; 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 13, 2026