

**K112071 WONDFO COCAINE URINE TEST MODEL W10-CU,
W10-P, WONDFO METHAMPHETAMINE URINE TEST MODEL
W11-CU, W11-P**Sep 23, 2011
65 days to decisionK112071 · Product code: **DIO** · Chemistry
Source: <https://www.510kdatabase.net/k112071/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jul 20, 2011
Decision date	Sep 23, 2011
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Wondfo Biotech Co., Ltd.
Location	Yardley, PA, US
Contact	Joe Shia
Website	https://www.wondfo.com.cn
510(k) history	43 submissions · 43 cleared · 2005-2026

Guangzhou Wondfo Biotech Co., Ltd. is a leading in vitro diagnostic (IVD) company founded in 1992. The company specializes in rapid point-of-care testing (POCT) devices and reagents. Wondfo operates with a manufacturing facility in Yardley, US, and serves over 150 countries globally. Wondfo has received FDA 510(k) clearances from total submissions since 2005. The company's regulatory portfolio is dominated by toxicology devices, including multi-drug urine test panels, cups, and dipsticks for substance screening. The latest clearance was in 2026, confirming active regulato...