

**K121557 WONDFO CANNABINOIDS URINE TEST WONDFO  
PROPOXYPHENE URINE TEST**Jul 25, 2012  
61 days to decisionK121557 · Product code: **LDJ** · Chemistry  
Source: <https://www.510kdatabase.net/k121557/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cannabinoids (LDJ)
Date received	May 25, 2012
Decision date	Jul 25, 2012
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Guangzhou Wondfo Biotech Co., Ltd.</b>
Location	Yardley, PA, US
Contact	Joe Shia
Website	<a href="https://www.wondfo.com.cn">https://www.wondfo.com.cn</a>
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...

---

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

Device record: <https://www.510kdatabase.net/k121557/> 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 June 14, 2026