

**K152495 Wondfo Propoxyphene Urine Test**Nov 23, 2015  
83 days to decisionK152495 · Product code: **JXN** · Toxicology  
Source: <https://www.510kdatabase.net/k152495/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Propoxyphene (JXN)
Date received	Sep 1, 2015
Decision date	Nov 23, 2015
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>LSI International, Inc.</b>
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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152495/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026