

**K043443 ONE STEP HCG URINE PREGNANCY TEST**Apr 8, 2005  
115 days to decisionK043443 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k043443/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Dec 14, 2004
Decision date	Apr 8, 2005
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Guangzhou Wondfo Biotech Co., Ltd.</b>
Location	Yardley, PA, US
Contact	HOWARD MANN
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...

---