

**K150022 Wondfo One Step HCG Urine Pregnancy Test Strip,
Wondfo One Step HCG Urine Pregnancy Test Cassette, Wondfo
One Step HCG Urine Pregnancy Test Midstream**Aug 7, 2015
213 days to decisionK150022 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k150022/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jan 6, 2015
Decision date	Aug 7, 2015
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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