

**K062703 ONE STEP HCG PREGNANCY TEST**Jul 23, 2007  
315 days to decisionK062703 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k062703/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Sep 11, 2006
Decision date	Jul 23, 2007
Days to decision	315 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ai DE Diagnostic Co., Ltd.</b>
Location	Iowa City, IA, US
Contact	LIN WANG
510(k) history	1 submissions · 1 cleared · 2007-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062703/> 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 28, 2026