

**K112449 QUIKRESPONSE ONE STEP MIDSTREAM EARLY  
PREGNANCY TEST**Sep 24, 2012  
396 days to decisionK112449 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k112449/>**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	Aug 25, 2011
Decision date	Sep 24, 2012
Days to decision	396 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tianjin New Bay Bioresearch Co., Ltd.</b>
Location	Carlsbad, CA, US
Contact	HANN-PING WANG
510(k) history	11 submissions · 11 cleared · 2005-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112449/>; 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 8, 2026