

**K965184 PERFECTA PREGNANCY TEST**Feb 4, 1997  
42 days to decisionK965184 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k965184/>**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	Dec 24, 1996
Decision date	Feb 4, 1997
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wyntek Diagnostics, Inc.</b>
Location	San Diego, CA, US
Contact	SHU-CHING CHENG
510(k) history	12 submissions · 12 cleared · 1995-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k965184/> 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 29, 2026