

**K981722 QUIDEL HOME PREGNANCY TEST**Jun 3, 1998  
19 days to decisionK981722 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k981722/>**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	May 15, 1998
Decision date	Jun 3, 1998
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quidel Corp.</b>
Location	Washington, DC, US
Contact	E. JOSEPH MCMULLEN
510(k) history	93 submissions · 93 cleared · 1983-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981722/> 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