

**K963341 MIDSTREAM ONESTEP PREGNANCY HOME TEST**Dec 2, 1996  
98 days to decisionK963341 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k963341/>**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 26, 1996
Decision date	Dec 2, 1996
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Syntron Bioresearch, Inc.</b>
Location	San Diego, CA, US
Contact	CHARLES YU
510(k) history	26 submissions · 26 cleared · 1987-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963341/> 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