

**K964002 NATURALE HCG PREGNANCY TES**Nov 7, 1996  
31 days to decisionK964002 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k964002/>**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	Oct 7, 1996
Decision date	Nov 7, 1996
Days to decision	31 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mizuho USA, Inc.</b>
Location	San Diego, CA, US
Contact	BENEDICT ZIN
510(k) history	7 submissions · 7 cleared · 1993-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964002/> 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