

**K203246 Atlas One Step hCG Urine Pregnancy Test (Strip),  
Atlas One Step hCG Urine Pregnancy Test (Cassette), Atlas One  
Step hCG Urine Pregnancy Test (Midstream)**Aug 4, 2021  
273 days to decisionK203246 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k203246/>**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	Nov 4, 2020
Decision date	Aug 4, 2021
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Atlas Link Technology Co., Ltd.</b>
Location	Langfang, CN
Contact	Xiaoping Hao
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203246/> 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 May 26, 2026