

**K241394 iHealth® Early Pregnancy Test**Dec 20, 2024  
218 days to decisionK241394 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k241394/>**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 16, 2024
Decision date	Dec 20, 2024
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	iHealth® Early Pregnancy Test Strip

**APPLICANT**

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Company	<b>Andon Health Co, Ltd.</b>
Location	Tiajin, CN
Contact	Liu Yi
510(k) history	92 submissions · 92 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241394/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026