

**K233624 HCG One Step Pregnancy Test Strip OTC, HCG One Step Pregnancy Test Strip Rx, HCG One Step Pregnancy Test Midstream OTC, HCG One Step Pregnancy Test Midstream Rx**Apr 12, 2024  
151 days to decisionK233624 · Product code: LCX · Chemistry  
Source: <https://www.510kdatabase.net/k233624/>**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 13, 2023
Decision date	Apr 12, 2024
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou Aichek Medical Technology Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Lisa Liu
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Dylan Wu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233624/>; 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 14, 2026