

**K240242 HCG Home Use Pregnancy Test Strip (Colloidal Gold),  
HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG  
Home Use Pregnancy Test Midstream (Colloidal Gold)**Oct 11, 2024  
255 days to decisionK240242 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k240242/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jan 30, 2024
Decision date	Oct 11, 2024
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Anhui Deepblue Medical Technology Co., Ltd.</b>
Location	Hefei, CN
Contact	Fengling Cheng
510(k) history	2 submissions · 2 cleared · 2024-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
Contact	Boyle Wang

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/k240242/> 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