

**K230741 Macro & Micro-Test HCG Pregnancy Test Midstream**Oct 13, 2023  
210 days to decisionK230741 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k230741/>**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	Mar 17, 2023
Decision date	Oct 13, 2023
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Macro &amp; Micro-Test Med-Tech Co., Ltd.</b>
Location	Nantong, CN
Contact	Bella Xu
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Sandra Jiang

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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230741/> 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 25, 2026