

K251053 Shinetell Plus™ Digital Early Pregnancy TestJul 15, 2025
102 days to decisionK251053 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k251053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Apr 4, 2025
Decision date	Jul 15, 2025
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou AllTest Biotech Co., Ltd.
Location	Hangzhou, CN
Contact	Rosa Wu
510(k) history	14 submissions · 14 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	Jenny Xia

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.netDevice record: <https://www.510kdatabase.net/k251053/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026