

K241978 Shinetell Digital Pregnancy TestAug 13, 2024
39 days to decisionK241978 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k241978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jul 5, 2024
Decision date	Aug 13, 2024
Days to decision	39 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)

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