FDA 510(k) Premarket Notification

CLEARED

K251053 Shinetell PlusTM Digital Early Pregnancy Test

Jul 15, 2025
102 days to decision

K251053 · 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